Arrow A*CAT*®1 Series

Intra-Aortic Balloon Pump (IABP) System

Operating Manual Addendum

Arrow International

NOTE: PLEASE ADD THIS ADDENDUM TO YOUR
A*CAT*®1 SERIES OPERATOR'S MANUAL

ADDENDUM ARROW A*CAT*®1 SERIES
Intra-Aortic Balloon Pump (IABP) System Operator's Manual

Part Number: IAM-9001–001, Revision 3

CE 0086

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Document Specification

When making reference to or requesting additional copies of this document, please note the following Part Number: IAM-9001–001, Revision 3.

CE 0086

INTRODUCTION

Arrow International, Inc. has made an ongoing commitment to product improvement and innovations. In keeping with this philosophy, we are pleased to release version 1.28 software for A*CAT*®1 Series Intra-Aortic Balloon Pump consoles. This version of software introduces several new operations, which are explained in this addendum.

The main operator's manual applies to software revisions of 1.25 and earlier. All warnings, cautions and operations in the main operator's manual apply to revision 1.28 and should be considered during pump usage. **This addendum applies ONLY to revision 1.28 software.** References to the main operator's manual pages related to the specific operation are made at the beginning of each section. Refer to the main operator's manual for additional information regarding these operations and functions.

BALLOON VOLUME

(Refer to Pg. 3-27 and 5-13 of the main operator's manual for additional information.)

The A*CAT*® 1 SERIES allows the user to set the precise volume to be delivered to the IAB in 0.5 cc increments. Volume can be changed while the pump is OFF or during pumping. If IAB volume is changed while pumping, the pump will pause for 1 or 2 beats to reset the volume and then resume pumping at the new volume setting.

> **CAUTION:** If IABP volume is changed while pumping patient support will be momentarily suspended as the volume is updated. Insure the patient will tolerate this procedure before pressing APPLY to initiate the volume change.

When the BALLOON VOLUME function key is pressed, the multi-function keys will change to the following:

When the balloon volume is changed, the following keys will appear:

Change Volume:

1. Press BALLOON VOLUME key.
2. INCREASE or DECREASE the volume to the desired setting.
3. Press APPLY to change volume.

   NOTE: Pump will reset volume in 1 or 2 beats and resume pumping.
4. If volume change was made in error, press CANCEL or wait 30 seconds for multifunction keys to time out.

Return to Full Volume:

1. Press BALLOON VOLUME key.
2. Press FULL VOLUME multifunction key.
3. Press APPLY to change volume.

   NOTE: Pump will reset volume in 1 or 2 beats and resume pumping. If volume change was made in error, press CANCEL or wait 30 seconds for multifunction keys to time out.

NOTE: If the volume is changed from the current delivered volume and then returned to that volume, the CANCEL and APPLY keys will disappear. These keys are only available when changing the volume from the current delivered volume setting.

NOTE: If the pump is in Stand-by when the volume change is made, the pump will go to OFF when APPLY is pressed. Press pump ON to start pumping at the new volume setting.

CHANGING IABP DELIVERED VOLUME (Pg. 5-13)

Press the BALLOON VOLUME key. The following multi-function key will appear:

When the INCREASE or DECREASE keys are pressed the CANCEL and APPLY keys will appear. When APPLY is pressed the selected volume will be implemented. If the volume change was in error, press CANCEL or wait 30 seconds the volume will remain at the current setting.

BALLOON VOLUME CHANGES WITH PUMP OFF

To change the IABP delivered volume while the pump is OFF, Press BALLOON VOLUME and INCREASE or DECREASE the volume until the desired volume is displayed, then press APPLY. When the pumping is initiated, the system will deliver the selected volume. To return to full volume, based on the IAB connector, Press BALLOON VOLUME, press FULL VOLUME, then press APPLY. The volume will be set to the IAB connector volume. When the pumping is initiated, the A*CAT*®1 will deliver the selected volume.

BALLOON VOLUME CHANGES WHILE PUMPING

To change the IABP delivered volume while pumping, press the BALLOON VOLUME key. Set the desired volume using the INCREASE and DECREASE keys. When the volume setting is changed, two additional function keys will appear, CANCEL and APPLY. To change the volume to the new setting, Press APPLY. The pump will pause briefly, reset the volume and restart the pump at the new volume. If you decide NOT to change the volume, wait 30 seconds until the display times out or Press CANCEL and the volume will remain at the current volume.

BALLOON VOLUME CHANGES WITH PUMP IN STANDBY

To change the IABP delivered volume while the pump is in STANDBY, press the BALLOON VOLUME key. Set the desired volume using the INCREASE and DECREASE keys. When the volume is changed, two additional function keys will appear, CANCEL and APPLY. To change the volume to the new setting, Press APPLY. The pump will go to OFF mode and the following message will appear:

PRESS PUMP ON TO START PUMPING
AT NEW SETTINGS

When PUMP ON is pressed the new volume will be delivered.

If you decide NOT to change the volume, wait 30 seconds from the last key press or until the display is cleared from the screen. You may press CANCEL at any time and the volume will remain at the currently delivered volume.

HELP

(Refer to Pg. 3-37/41 of the main operator's manual for additional information.)

KEY 1	KEY 2	KEY 3	HELP MESSAGE TEXT
HELP	**BALLOON VOLUME**		Select INCREASE/DECREASE until desired volume is displayed. Press FULL VOLUME to return to volume based on balloon connector. If pump is pumping, Press APPLY to change volume or Press CANCEL to cancel changes made.
HELP	**AP SELECT**		AP SELECT provides selection for source SCALE, AP Alarm, ZERO and CAL. To change input source, press AP SELECT again. Press AP SCALING to select scale. To zero, open transducer to air and press ZERO. To CAL, input 100mmHg and adjust sens.AP alarm on MAP/PDP, press ON, set limit.

MULTIFUNCTION KEY HELP			
HOME	HELP	**WEANING SETUP**	WEANING SETUP sets volume, assist ratio and time for a weaning session. Select parameter and change using the < and > keys. Press START to begin weaning. A timer is displayed on the main screen. Press the 100% V @ 1:1 key X 2 to cancel Weaning and Resume full support.
HOME	HELP	**HEMODYNAMICS**	Calculates two pressure differences from AP: (PDP - PSP) and (PDP - BAEDP). Calcs based on last assisted beat. AP values frozen for 30 seconds. Press HEMO to unfreeze. If assist ratio is 1:2 or lower, the Unassisted values will show in YELLOW.
HOME	HELP	**FLASH CARD**	The Flash Card allows start up settings for the *ACAT*® to be modified. Place card in receptacle and POWER ON pump or press HOME and SHOW STATS to select Flash card settings. To program card, select ALL settings using keypad, then press HOME and SAVE TO FLASH.

FLASH CARD

(Refer to Pg. 5-5 of the main operator's manual for additional information.)

The *ACAT*® 1 SERIES has the ability to alter the start up settings of the pump using a Flash Card. This Flash Card may be changed by the clinician to suit individual or institutional preferences. The following section is a guide to the use and programming of the Flash Card.

STARTING THE SYSTEM USING FLASH CARD SETTINGS

If a Flash Card has been programmed, place the Flash Card in the receptacle, prior to power ON. With the Flash Card in place, Power ON the pump. Altered settings, based on the Flash card will now be used. The following advisory message will appear:

> ALTERED SETTINGS IN USE, TO CHANGE TO ACAT STARTUP SETTINGS PRESS HOME, SHOW STATS AND ACAT PRESET SETTINGS KEY

If the pump is already powered ON, the Flash card settings can still be implemented. Place the Flash Card in the receptacle, a Beep will sound, indicating the pump recognizes the Flash Card. Press HOME and SHOW STATS. The following multifunction keys will appear:

Press FLASH CARD SETTINGS and the settings of the pump will become the altered settings from the Flash Card. An advisory message:

> FLASH CARD SETTINGS IN USE will be displayed.

> **NOTE:** The pump must be OFF (not pumping) to implement Flash Card Settings

WARNING

Be prepared to change settings in the event that the Flash Card settings are NOT compatible with the current requirements of the patient. Settings, which may need to be altered, include, Trigger mode, timing settings, assist ratio, balloon volume and ECG/AP source selections. Implementing Flash Card settings while the pump is connected to a patient should be done with extreme caution.

RETURNING TO A*CAT*® PRESET START UP SETTINGS

If the user prefers to return to the A*CAT*® 1 Preset start up settings or the Flash Card settings are used in error, this can be done by pressing HOME, SHOW STATS and the PRESET SETTINGS. PRESET SETTINGS key must be pressed TWICE to implement these settings. When the key is pressed a second time, the A*CAT*® 1 settings will be returned to the Default start up settings.

A*CAT*® 1 preset settings can only be initiated from the multifunction keys if a Flash card is in the receptacle, even if the Flash card settings are not in use. Choosing this function will reset all current selections to the initial default settings.

Default start-up settings are:	
Pump:	OFF
Assist ratio:	1:2
ECG:	Skin, Lead II Autogain ON
AP:	Transducer, Scale 50 - 150 mmHg
Trigger mode:	Pattern
Timing settings:	Inflation 50% and Deflation 85% (Pattern trigger)
Alarms:	ON
Balloon Volume:	Full volume based on IAB connector
Recorder:	ECG/AP @ 25 mm/sec
Cursor:	Top of AP waveform
AP Alarm:	OFF

SAVING SETTINGS TO THE FLASH CARD

Verify that the Flash Card is NOT write protected. (A small switch is located on the end of the Flash Card opposite the connector. See the reverse side of the Flash Card for write protect position.)

Place the Flash Card in the receptacle. Using the A*CAT*® 1 keypad controls set ALL parameters to the desired settings. You will not be able to select some settings, such as INT trigger, but most other settings can be selected. The settings, which can be altered, include both hard key operations such as Trigger modes and multifunction key functions such as Recorder setup and Audio setup and AP alarm settings.

SAVING SETTINGS TO THE FLASH CARD (continued)

When all parameters are selected, Press HOME and SHOW STATS. Press SAVE TO FLASH. You will be asked to confirm this selection by pressing this key again. When the key is pressed a second time, the current settings will be saved. If the Flash Card is not in place or is write protected, an Error message will appear:

> CANNOT SAVE TO FLASH, NO FLASH CARD OR
> FLASH CARD WRITE PROTECTED.

If this occurs, re-install the Flash Card and/or check that the write protect is OFF. If this error continues, contact Field Service.

WEANING SETUP/START

(Refer to Pg. 3-47 and 5-22/23 of the main operator's manual for additional information.)

In addition to the use of the Assist Ratio and Balloon Volume keys on the A*CAT*®1 keypad to select the desired weaning parameters, the A*CAT*®1 has the facility to select and change these parameters and set a time for these reduced settings. At the end of the selected time period, the user will be alerted to check the patient hemodynamic status and continue weaning or resume full IABP support.

To implement Weaning with the timer, Press HOME and WEANING SETUP. The following options will appear:

Press the parameter key, which you want to change, note it will become highlighted. Press the same key again and the following keys will appears:

Use the < and > keys to set the parameter to the desired setting. When all settings are made, press START WEANING. When the START WEANING key is pressed, the pump will implement the new assist ratio and volume settings. This will cause the pump to pause for 1 or 2 beats to make these adjustments. When weaning is started the following keys will appear and a warning message "WEANING" will be displayed above the ECG in the warning/alert message area of the LCD.

The timer will indicate the time remaining for these weaning settings. The seventh multifunction key will change from START WEANING to 100% VOL @ 1:1. This key is used to stop weaning and immediately return to full support at 100% IAB volume based on the IAB connector at 1:1 assist ratio. The timer and the Full Support key will remain in the multifunction key area whenever the weaning mode is in use.

STOP WEANING

Weaning can be suspended or terminated in several ways.

1. 100% VOL. @ 1:1 Key: This key will immediately stop weaning and resume full support at 100% Volume and 1:1 assist.
2. Changing assist ratio: If the assist ratio is changed while weaning is in use, the weaning program will be suspended. All previous weaning settings will be retained for future use.
3. Changing IAB volume: If the IAB volume is changed while weaning is in use the weaning program will be suspended. All previous weaning settings will be retained for future use.

WEANING STEP COMPLETE:

When the timer expires for a weaning step, a Class 3 alert will be displayed:

WEANING STEP COMPLETE

EVALUATE HEMODYNAMICS AND CONTINUE
WEANING OR RESUME FULL IABP SUPPORT

Current IAB volume and assist ratio from the weaning setup will be used for pumping until another weaning setup is selected or until pumping is discontinued.

WEANING AND INTERNAL TRIGGER MODE

Weaning cannot be set when INTERNAL trigger mode is selected. The user must change to another trigger mode if the weaning mode is required.

If you are in weaning and the INTERNAL trigger mode is selected and confirmed by pressing the INTERNAL key twice, weaning will be suspended and the INTERNAL mode will be selected.

CAUTION: Decreased IAB volume and decreased assist ratio, when used in combination with each other, may DECREASE IAB movement and INCREASE the risk of thrombus formation on the surface of the IAB. Carefully consider the combination of these settings.

NOTE: IAB volume cannot be reduced more than 50% of the IAB connector volume in the weaning setup. Generally, IAB volume should not be reduced more than 30% of the full volume.

ARTERIAL PRESSURE ALARM

Refer to pages 3-24/25 and 5-10/11 for further information on the AP SELECT function.

Changes in the patient hemodynamic condition or an arterial pressure tubing disconnect may occur during counterpulsation. Revision 1.28 software allows the user to select one of two parameters, the Mean Arterial Pressure (MAP) or the Peak Diastolic (PDP) or augmented pressure to monitor for these conditions.

TURNING THE AP ALARM ON

The start-up default setting of the AP alarm is OFF. In order to select a parameter and set the alarm limit, the user must turn on the AP alarm. To do so, Press AP SELECT and the following will appear:

Press AP OFF key and the following will appear:

The following message will appear:

"SELECT PARAMETER FOR AP ALARM
USE < AND > KEYS TO SET LIMIT"

SELECTING THE AP PARAMETER FOR ALARM AND SETTING THE ALARM LIMIT

Once the AP alarm is on, Multifunction key 3 can be used to select either the MAP or PDP as the parameter for the alarm. Each press of MF3 will toggle between the two selections. MAP is the default settings when the alarm is turned on initially. Once the alarm parameter is selected, the alarm limit can be set (adjusted) by using the < and > alarm limit keys. The default alarms settings are:

Parameter	Initial limit	Alarm limit range
MAP	70 mmHg	30 to 120 mmHg
PDP	100 mmHg	50 to 250 mmHg

The limits can be increased or decreased in 5 mmHg increments.

The current limit will be displayed in YELLOW on the left side of the LCD, between the AP Scale information.

The following message will appear when the < and > limit keys are pressed:

"INCREASE OR DECREASE CURRENT ALARM LIMIT
CURRENT ALARM LIMIT: XXX MMHG"

AP alarm information, ON/OFF, AP parameter selected and AP alarm limit will be printed on the recorder strip.

CAUTION: The alarm limit should be set low enough to reduce the risk of intermittent alarms due to minor changes in the patient condition, but not so low that serious deterioration of the hemodynamic status is not detected.

ALARM CONDITIONS

When the MAP or PDP is below the alarm limit for a specified period of time, a Class 3 Alert will sound and the following message will be displayed:

ARTERIAL PRESSURE ALARM
ARTERIAL PRESSURE HAS FALLEN BELOW SET LIMIT:

1. CHECK AP FOR DISCONNECT
2. ASSESS PATIENT HEMODYNAMICS
3. RESET ALARM LIMIT

The time to alarm will vary depending on the parameter selected for the alarm and the assist ratio of the pump.

MAP: The MAP alarm will be issued when the MAP is below the alarm limit for 8 consecutive seconds. This alarm is available when pumping and when not pumping.

PDP: The PDP alarm is only available while pumping, since this is the only time the PDP is present. If the pump is in 1:1 or 1:2 assist, the alarm will be issued when the PDP is below the alarm limit for 5 consecutive beats. When the assist ratio is 1:4 or 1:8 the alarm will be issued within 30 seconds, independent of how many assisted beats have occurred. This will prevent alarms on 1 or 2 assisted beats only.

CAUTION: If the AP alarm is being used primarily to monitor for AP disconnect, the MAP should be used, as the alarm is available when the pump is pumping and when the pump is not pumping. The PDP alarm is only available when the pump is pumping. This may not alert the user to disconnection under all conditions.

The alarm will automatically reset if the selected parameter goes above the alarm limit. The user can also reset the alarm manually be pressing the RESET key.

If the alarm has been manually reset and the AP parameter remains below the alarm limit for 3 consecutive minutes, the audio alarm will sound again. The alarm message will remain on the screen as long as the alarm limit is violated.

It is important to assess the patient hemodynamics and also check for disconnects in the AP set-up. If the alarm limit is too high, the user should consider resetting the limit.

If you change AP SOURCE during the AP alarm, and the new AP source is above the alarm limit, the alarm will be reset. It is important to check the original AP SOURCE where the alarm was detected to verify that no disconnect has occurred.

CAUTION: Switching the AP SOURCE during an AP alarm could reset the alarm even if a serious condition, such as a tubing disconnection has occurred. Even if the alarm has been reset, the user should verify that the AP source (transducer or monitor) lines are intact and that bleeding from the source of the AP alarm has not occurred.

HEMODYNAMIC CALCULATIONS AND CHARTING HEMODYNAMIC VALUES

(Refer to pg. 3-50 of the main operator's manual for additional information.)

In order to make the hemodynamics more stable for charting, a new feature has been added to the HEMODYNAMICS multifunction key. When HOME and HEMODYNAMICS are pressed, the calculations will appear as described in the operator's manual AND the numeric values will freeze on the display for 30 seconds.

The HEMODYNAMICS key will be highlighted in WHITE when the AP values on the display are frozen.

NOTE: The IABP must be pumping in order for AP values to be frozen and calculations to be performed. If the pump is in OFF or STANDBY, the user will be prompted to press pump ON to calculate and freeze the AP values.

If the HEMODYNAMICS key is pressed while the numeric values are frozen, the values will begin updating the most current hemodynamics on a beat to beat basis.

If the pump assist ratio is set at 1:2 or lower, the UNASSISTED values will also appear on the display. These will be in YELLOW and appear directly below the assisted value, which is the larger WHITE displayed value. The UNASSISTED values will also appear in a smaller size font.

If the assist ratio is changed while the AP values are frozen, the values will begin updating on a beat to beat basis. The following message will appear in the key prompt area:

"ASSIST RATIO HAS CHANGED,
PRESS HEMO KEY AGAIN TO FREEZE AP VALUES"

When 30 seconds has expired, the pump will resume updating the hemodynamics on a beat to beat basis.

If the pump is OFF and HEMODYNAMICS is pressed, the following message will appear:

"PRESS PUMP ON, THEN HEMO KEY
TO CALCULATE AND FREEZE AP VALUES"

CAUTION: The frozen hemodynamics may not represent the actual patient condition if there is wide variation in the heart rate and rhythm. The user should verify that these values reflect the actual hemodynamic condition prior to using them as the basis of treatment decisions.

CAUTION: The user should continue to monitor the displayed waveforms on the LCD, since these reflect the current condition of the patient and may show a significant change in patient condition which warrants clinical intervention.

RECORDER UPDATES

See pages 3-46 and 5-21 of the main operator's manual for additional information on recorder set-up and functions.

Several additions have been made to the recorder strip. These include:

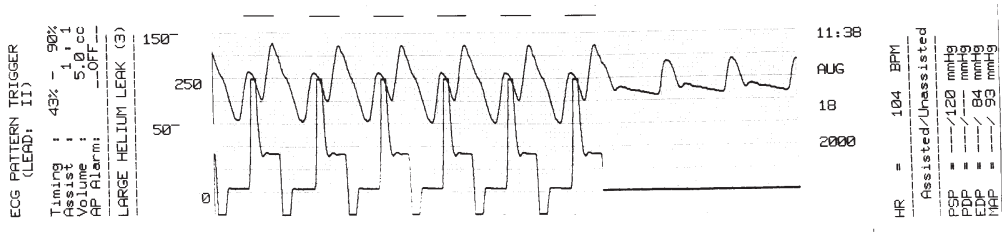
Addition of both Assisted and Unassisted AP values to the end of the strip. The A*CAT*®1 will print one set or both sets of values depending on the pump status. The values will be printed side by side at the end of the strip.

These values represent the last fully printed beat. If the pump is in an assist ratio of 1:2 or lower, the Assisted values will represent the last ASSISTED beat. This may or may not be the last fully printed beat on the recorder strip.

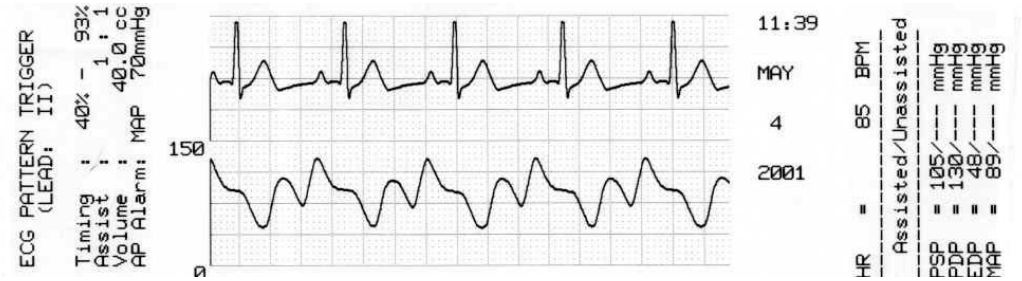
The AP alarm status has been added to the header of the strip. This will document whether the AP alarm is ON or OFF, which parameter is being monitored and the alarm limit for the currently monitored parameter.

When an alarm is printed, if a subcode, which further defines the cause of the alarm, is available, it will be printed after the alarm message.

STRIP 1: Alarm strip: Note subcode printed after alarm header

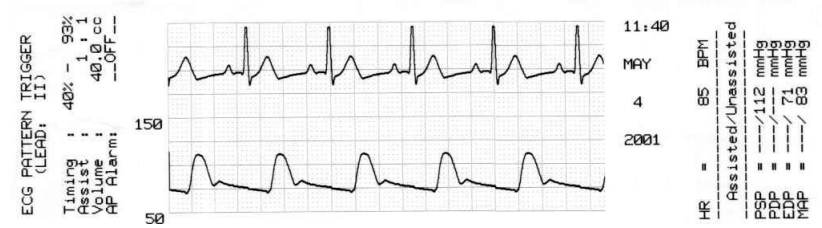


STRIP 2: PUMP ON, MAP alarm ON, AP Assisted values printed.



STRIP 3: PUMP ON 1:2 Assist, Both Assisted and Unassisted AP values printed, AP alarm ON for PDP.

STRIP 4: PUMP OFF, Unassisted AP values printed, AP alarm OFF.



ALARMS AND TROUBLESHOOTING

See section 9 for additional information on alarms and troubleshooting.

AUTOMATIC RESPONSE ALARMS (CLASS 1)		
Alarm	**Possible Causes**	**Corrective Actions**
UNABLE TO REFILL (Replaces HELIUM LOSS 1 alarm)	Low HE tank pressure	Verify HE tank is ON and has adequate HE supply. If HE tank pressure is less than 100 psi or HE tank display is RED, change tank.
	Timing settings are too wide for current heart rate and rhythm	Adjust timing settings to proper timing. Change trigger mode to rate PEAK or PATTERN.
	Fill valves not functioning correctly	Change to another console. Call Field Service.
	Very Large HE leak	Check for blood in tubing, if blood is found, stop counterpulsation and remove IAB. Assess for large leak in tubing or connections. Repair as directed on page 9-20.

INFORMATION ONLY ALARMS (CLASS 3)		
Alarm	**Possible Causes**	**Corrective Actions**
AP HAS FALLEN BELOW SET LIMIT	AP disconnect	Check AP lines for disconnection, reconnect and reflush.
	Arterial pressure has dropped.	Assess patient condition and treat according to hospital protocol. Change AP alarm limit.
	AP alarm limit set too high	Change AP alarm limit.
WEANING STEP COMPLETE	Weaning timer has expired	Assess patient hemodynamics, and set next step of weaning. Press START weaning.
		If Hemodynamic status is unstable, resume full IABP support by pressing the 100%V @ 1:1 key X 2 or increasing IAB volume and/or assist ratio.

ORDER INFORMATION

See section 8 (pg. 8-18-21) for additional order information.

ACAT®1 SERIES MODEM SOFTWARE		
Name	**Part Number**	**Description**
ACAT®1 MODEM PC PROGRAM	IAM-2000	PC Software for connecting modem to *ACAT*®1 series IABP systems. Includes installation software, connection software and Operator's manual.

SPECIFICATIONS UPDATES

See section 4 (pg. 4-5) for additional order information.

ACAT®1 SERIES PACER DETECTION (and Rejection) CRITERIA	
Specification	**Description**
PACER DETECTION Low level (skin) ECG input	Width of .1 to 2 msec and Amplitude of ≥ 2mV
PACER DETECTION High level (Monitor) ECG input	Width from .1 to 5 msec and Amplitude of ≥1 V
NOTE: Pacers automatically detected and rejected in PATTERN, PEAK and AFIB trigger modes. Pacers are automatically detected and used for triggering in APACE and VPACE trigger modes.	

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Arrow *ACAT*®1 Series

Intra-Aortic Balloon Pump (IABP) System

Operating Manual

Arrow International

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Intra-Aortic Balloon Pumping (IABP), or counterpulsation, is a widely accepted therapeutic method of temporarily supporting patients with impaired left ventricular function. Impaired left ventricular function causes low cardiac output and inadequate coronary perfusion. Counterpulsation helps to balance the myocardial oxygen supply and demand in these patients. The hemodynamic effects of counterpulsation are immediate, predictable, and most importantly, decrease morbidity and mortality. The IABP can be initiated rapidly. For this reason, the IABP has become an important therapeutic tool in a variety of clinical settings, including Emergency Departments, Cardiac Catheterization Labs, Operating Rooms, and Intensive Care Units.

This chapter provides an overview to the clinical uses of the IABP and the functions of the A*CAT*®1 IABP System. The details of how the A*CAT*®1 works is described in Chapter 3, Principles of Operation.

The contents of this chapter include:

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Physiological Basis of IABP

The overall goal of IABP is to provide cardiac support to patients whose myocardial oxygen supply and demand are imbalanced. Counterpulsation achieves this goal by increasing coronary and systemic perfusion, decreasing afterload (myocardial work) and decreasing preload.

The IABP exerts its effect by rapidly shuttling helium gas in and out of the balloon chamber. At a precisely timed interval, the gas enters the balloon chamber within the aorta. As the gas is shuttled into the balloon, it occupies a space within the aorta equal to its volume. The usual adult balloon volume is 40cc although alternate sizes (30 and 50cc) may be better tolerated clinically. The sudden occupation of space by the gas upon inflation causes blood to be moved from its original position. The blood is moved superiorly and inferiorly to the balloon. Along with the movement of blood is a sharp increase in the pressure in the aorta. Since the volume in the aorta is suddenly increased and the aortic wall is fairly rigid, the intra-aortic pressure increases sharply.

With deflation of the IAB, the sequence of its effects is reversed. A sudden 40cc fall in aortic volume causes a sudden decrease in aortic pressure within that localized area. In response to the fall in pressure, the blood in adjacent areas moves to equalize the pressure within the aortic cavity as a whole. The evacuation of 40cc of volume from the aorta is timed to occur precisely prior to ventricular ejection (systole).

Displacement of blood volume (both away from the balloon on inflation and toward the balloon on deflation) is the mechanism by which the IABP alters the patient's hemodynamic state. To alter the hemodynamic state for the greatest benefit, the IABP must be set so that inflation and deflation of the balloon occur at the optimal times.

To provide maximum benefit to the patient, the IABP must be provided with a reliable trigger so that the assist occurs consistently in each cardiac cycle. ECG triggering utilizing the R-wave or the QRS complex is usually the simplest way to accomplish this, and is the preset mode used by the IABP. In addition, inflation and deflation points must be timed very precisely. Optimum timing results in increased Peak Diastolic Pressure (PDP) and decreased Balloon Aortic End-Diastolic Pressure (BAEDP). If the balloon is inflated too early, Stroke Volume (SV) may be reduced. Late inflation will result in smaller increases in PDP and perfusion. If the balloon is deflated too early, BAEDP (and thus workload) is not decreased. Late deflation is more serious, because BAEDP (i.e. workload) may be increased, causing a further imbalance in myocardial oxygen supply and demand. After you have optimized timing, the A*CAT*®1 automatically adjusts for most variations in the patient's heart rate and for arrhythmias.

Extensive clinical experience shows that Intra-Aortic Balloon Pumping is a safe and effective method of providing cardiac assist to appropriate patients[20]. By increasing coronary and systemic perfusion and decreasing preload and afterload, the IABP can stabilize critically ill cardiac patients. It is important to initiate IABP as quickly as possible to help minimize further damage to the myocardium. Medical and surgical indications for IABP are described in the following section.

Medical Indications

Cardiogenic Shock[2,6,9,10,13,14,17,27,28,29]

Cardiogenic shock is a physiological derangement of circulatory failure due to severe depression of myocardial function. Cardiac Output (CO) is markedly depressed and the compensatory mechanisms that usually maintain CO (e.g., increased Heart Rate [HR], increased preload and increased contractility) are no longer sufficient to return systemic perfusion to a life supporting level. CO is further compromised by the loss of contributing myocardium to the contractile process. During cardiogenic shock, further deterioration occurs as a result of dysfunctional compensatory mechanisms, resulting in a vicious cycle that increases the stress on an already over stressed myocardium. Cardiogenic shock may result from several conditions, the most common is following Myocardial Infarction (MI).

Hemodynamic variables are manipulated with pharmacologic agents to break the cycle of cardiogenic shock. It is generally accepted that pharmacologic agents should be used as a first line of therapy. Drug intervention, however, cannot cause increased perfusion to the coronary artery system. In an ischemic state, the coronary arteries are already maximally dilated and are totally dependent on the perfusion gradient. The ability to autoregulate coronary flow is lost.

IABP can help to increase coronary perfusion. The reduction in afterload and the increase in systemic perfusion pressure are also advantageous. Most practitioners agree that early use of IABP increases the probability of survival. IABP should be considered if first line medical therapies do not improve the patient's clinical status within two to three hours. Further losses of viable myocardium can occur if inadequate perfusion is allowed to continue.

The A*CAT*®1 should only be used under supervision of qualified medical personnel. An external patient monitor must be used with the A*CAT*®1. The external monitor must have alarms for high and low blood pressure enabled.

Pre-shock Syndrome[2,13]

Pre-shock syndrome is a condition of deteriorating cardiac function secondary to myocardial ischemia, infarction or mechanical defects. The hallmark signs are decreasing CO, increasing afterload resulting from initial compensatory mechanisms, increasing preload caused by failing cardiac function and the initial signs of generalized systemic myocardial ischemia.

IABP therapy is indicated if first line therapies do not reverse the condition and the patient is still salvageable. Myocardial cells are at risk for irreversible damage. Time is critical because the IABP may prevent further deterioration and provide time for the myocardium to heal before infarction occurs.

Threatening Extension of MI[16,17,18,23]

If signs of myocardial ischemia continue after an infarction, a portion of the myocardium is in jeopardy. IABP may salvage viable myocardium in these patients. The IABP can be used to alleviate the hemodynamic instability caused by myocardial ischemia while the physician evaluates further intervention options (e.g., coronary bypass surgery). Early intervention is important.

Unstable Angina[18]

Angina is a sign that oxygen supply to the heart is inadequate. Angina sometimes becomes resistant to usual modes of therapy, and the pain continues. Patients with intractable angina often find dramatic relief within 15 minutes of instituting IABP support. This allows time for further evaluation of patient symptoms.

Intractable Ventricular Dysrhythmias

Ventricular irritability may result from islands of ischemic myocardium. Cell membranes of the hypoxic cells become unstable and discharge electrical currents in a disorganized manner. IABP can relieve the hypoxic environment of the irritable cells by increasing coronary artery perfusion. Reduced myocardial oxygen demand may also help patients with these dysrhythmias.

Septic Shock Syndrome[21]

Septic shock is a state of vascular collapse due to a fall in systemic blood pressure. Bacterial endotoxins paralyze the pre-capillary sphincters, causing a fall in blood pressure. These pre-capillary sphincters are paralyzed in the open position and are unable to maintain a driving pressure for tissue perfusion. At the onset of septic shock syndrome, CO is very high (maintained by elevated Stroke Volume [SV] and HR) and Systemic Vascular Resistance (SVR) is very low. Late in the course of septic shock, profound vasoconstriction increases SVR and decreases CO. Also, it is thought that circulating myocardial depressant factors begin to impair myocardial contractility in the later stages of this syndrome. CO falls, and the patient's condition deteriorates rapidly. In addition, the tissues become unable to utilize the oxygen that is delivered, and increased arteriovenous shunting of oxygen occurs.

The IABP has been employed in some cases of septic shock, generally when the patient is known to have compromised myocardial function. In the early stages of the syndrome, when coronary perfusion is low due to arterial vasodilatation, the IABP may help to increase Coronary Perfusion Pressure (CPP) and supply the heart with extra oxygen. In the late stages, IABP may benefit the patient by reducing afterload when vasoconstriction becomes prominent.

Cardiac Contusion[26]

Contusion with subsequent infarction of the myocardium can occur with trauma to the chest wall. The majority of cases of myocardial contusion result from automobile accidents and other blunt chest trauma. Aneurysms involving the contused area can occur.

The necrosis of contused cardiac tissue is very similar to infarction from Coronary Artery Disease (CAD). The acute phase of contusion is characterized by hemodynamic instability, and cardiogenic shock is not uncommon in severe cases. These patients benefit from IABP in much the same way that patients with cardiogenic shock caused by a coronary event benefit from IABP. However, many patients with cardiac contusion are young and without coronary disease. The infarction involves a discrete area and is much less diffuse than infarction caused by coronary obstruction. The long-term prognosis is far better in patients with necrosis caused by contusion if they survive the acute phase. IABP is indicated if conservative measures do not restore hemodynamic stability.

Prophylactic Support During Diagnostic Interventional and Non-surgical Procedures[3,8,12]

Patients undergoing ischemic events are sometimes candidates for cardiac catheterization, coronary angioplasty stents, thrombolytic therapy or coronary atherectomy. Cardiac catheterization is necessary to identify the obstructed arteries that may be successfully treated by coronary bypass surgery. In hemodynamically unstable patients, the catheterization procedure can be hazardous because coronary artery supply is temporarily interrupted during injection of the radio opaque dyes. This interruption of the already inadequate oxygen supply can precipitate sudden deterioration of myocardial functions. Use of IABP increases the probability that angiographic studies can be completed in a controlled manner.

Coronary angioplasty may be contraindicated in a hemodynamically unstable patient with an otherwise correctable lesion. Inflation of the angioplasty balloon temporarily obstructs coronary blood flow. The use of IABP may help to stabilize the patient's hemodynamic condition and increase coronary reperfusion by increasing CPP.

In addition, studies have shown that IABP use after emergency or high risk primary PTCA for acute MI reduces reocclusion and may add strength to reperfusion and improvement of LV function[10,14,15,22].

Coronary atherectomy may be indicated in specific types of coronary lesions. IABP may support this interventional procedure[24].

Mechanical Defects

Mechanical defects that impede forward CO are another group of medical indications for IABP. These defects include valvular stenosis, valvular insufficiency and ventricular septal defect.

Valvular Stenosis

The two types of valvular stenosis are aortic stenosis and mitral stenosis. In **aortic stenosis**, a narrowed valve opening obstructs left ventricular ejection. The left ventricle must generate a higher pressure for a longer period of time to achieve ejection. The left ventricle hypertrophies in response to chronic systolic pressure overload. The pressure during systole greatly increases wall pressure, but this is offset somewhat by the increased wall thickness. The heart functions at its limits of oxygen supply. Indeed, angina is a hallmark of aortic stenosis. Concurrently, CO becomes "fixed" due to the restricted valve orifice. Patients with symptomatic aortic stenosis are in danger of sudden death, presumably due to an ischemic dysrhythmias. The IABP can be used to maximize coronary artery pressure until surgery can be performed. The value of afterload reduction is limited because orifice size, not aortic pressure, prevents left ventricular ejection.

Mitral stenosis causes diastolic ventricular underloading. The mitral valve orifice becomes small and restricts the diastolic filling of the left ventricle. As the valve narrows, blood collects in the left atrium and pulmonary circuit. The ventricle becomes dependent on a high left atrial pressure to facilitate left ventricular filling. CO becomes "fixed" because the amount of blood the left ventricle can empty is restricted by the amount it receives. The high pressures and the blood dammed against the stenotic mitral valve cause respiratory insufficiency. Patients often present with pulmonary hypertension and pulmonary edema. Arrhythmias, which can limit coronary filling and jeopardize the myocardium, are associated with a decompensated state of mitral stenosis. The goal of IABP therapy in mitral stenosis is to maximize coronary artery perfusion while further treatment decisions are being made. Afterload reduction has little value because the heart is incapable of increasing its CO. However, afterload reduction may be desirable following valve replacement if left ventricular failure occurs.

Mitral Valvuloplasty

In the event that Mitral Valvuloplasty is chosen as a therapeutic intervention, the IABP may be used to maximize coronary artery perfusion and reduce afterload immediately before and/or after the procedure. The IABP mechanisms of action are the same as those described for mitral stenosis.

Mitral Valve Insufficiency

The two types of valvular insufficiency are aortic insufficiency (see Section 1.2) and mitral insufficiency. In **mitral insufficiency**, the leaflets of the valve become unable to seal off the left atrium from the left ventricle during systole. As a result, a portion of the left ventricle's contents is ejected backward into the left atrium. The left ventricle works under a condition of chronic volume overload and ejects its contents into a relatively low-resistance left atrium. In spite of severe myocardial dysfunction, the heart is able to maintain CO because of the low impedance to ejection. Most of the energy expended is used in fiber shortening instead of tension development. Therefore, the Isovolumetric Contraction (IVC) phase is shortened and myocardial oxygen demand is reduced.

Mitral insufficiency causes fatigue and chronic pulmonary vascular congestion. The left atrium becomes dilated and the left ventricle hypertrophies. If mitral insufficiency is sudden, the heart cannot compensate completely and the patient presents with florid pulmonary edema and cardiogenic shock. It is important to reduce afterload because decreased aortic pressure enhances forward CO and minimizes regurgitation into the left atrium. The IABP may be necessary if pharmacologic agents do not reduce afterload adequately. Reduction of afterload by IABP may be the key to survival following valve replacement. When the incompetent valve is replaced, the left ventricle is forced to eject its full SV into the high pressure aorta. Myocardial workload increases dramatically with the increase in the IVC phase. If the myocardium is dysfunctional (which may not be apparent preoperatively), mortality will be high if myocardial workload is not reduced adequately.

Ventricular Septal Defect (VSD)

In VSD, blood is shunted from the left ventricle to the right ventricle with each ventricular contraction (The pressure on the left side of the heart is greater than that on the right.). As blood is shunted to the right side, the SV ejected into the aorta is decreased and right ventricular pressures rise. Blood begins to pool in the systemic venous circuit because the right ventricle is unable to contain the extra volume it receives from the left ventricle.

Systemic venous congestion is the main symptom of VSD. The patient may not show signs of congestive heart failure until the end stages of the disease because there is no obstruction from the pulmonary artery to systemic circulation. IABP increases SV by providing a favorable pressure gradient (with balloon deflation). The left ventricle empties more completely at a lower aortic pressure because less blood is shunted across the septum into the right ventricle. The right ventricle, in turn, is able to empty more completely because the end-diastolic volume is less, relieving wall tension. Right ventricular function is improved and the symptoms of venous congestion lessen.

Surgical Indications

Prophylactic Preparation for Cardiac Surgery[5,8,19,20,28]

Induction of anesthesia can be stressful to the cardiovascular system. Several drugs can increase myocardial oxygen demand by increasing HR, SVR or contractility. The stress of surgery can cause similar reactions. It may be appropriate to use IABP in patients with limited myocardial reserves, including patients with:

- unstable angina
- triple vessel disease (all major coronary arteries obstructed)
- left main disease (proven to carry higher mortality and morbidity rates)
- recent MI (within six weeks)
- impending MI
- poor LV function (EF <25%)[4]

The IABP can also be used in conjunction with investigational devices (i.e., LVAD, RVAD, CPS, etc.), if the indication for use of the device is among those listed above as currently approved indications for IABP therapy (e.g., cardiogenic shock, VSD, MI, unstable angina, etc.)

Any hemodynamically unstable patient may benefit from IABP, whether undergoing cardiac or non-cardiac surgery[5,8]. The main objectives are to maintain a margin of safety in myocardial oxygen balance in the pre-bypass or anesthesia induction period and to support the heart in the event of dysfunction in the early postoperative period.

Post-surgical Myocardial Dysfunction[20]

Post-surgical myocardial dysfunction is popularly known as “post-pump syndrome” or “low cardiac output syndrome”. The etiology is not fully known. The low CO following surgery reflects a global depression of myocardial function. Some proposed etiologies include depression caused by drugs, alterations in perfusion from the cardiopulmonary bypass and intraoperative hypotensive occurrences. The syndrome disappears and cardiac function returns in 24 to 36 hours when appropriate therapies are given. Prognosis is generally very good if baseline cardiac function is near normal and intraoperative infarction is absent.

Cardiac Support Following Correction of Anatomical Defects

Patients undergoing correction of a VSD or mitral valve replacement for mitral insufficiency frequently need cardiac support following surgery. After repair of these defects, the myocardium must overcome a higher afterload in order to eject the SV. IABP support may be more long term if it takes time for myocardial function to return to normal.

Maintenance of Graft Patency Post Coronary Bypass Surgery

IABP may not be needed to maintain graft patency after coronary bypass surgery. IABP may be appropriate if cardiac function is compromised and graft patency is jeopardized.

Pulsatile Flow During Cardiopulmonary Bypass

This is not an indication in and of itself. The value of pulsatile flow is debatable and has not been resolved. Some cardiopulmonary bypass machines are capable of providing pulsatile flow or can be adapted to deliver pulsatile flow. In most cases, there must be an additional reason to warrant the use of IABP.

Bridge to Left Ventricular Assist

Patients who exhibit significant hemodynamic compromise despite IABP therapy, may require more intensive Left Ventricular Support.The IABP may be used until other such devices can be implemented.

Contraindications

Intra-Aortic Balloon Pumping (IABP) requires an adequate location in which to place the balloon and a functional aortic valve. Further, the clinician must have confidence that the patient will benefit from the procedure. The conditions described below are contraindications.

Absolute

Hemodynamically Significant Aortic Valve Insufficiency

If an aortic valve is incompetent, inflation of an IAB will result in increased regurgitation into the left ventricle. The flow of blood back into the left ventricle will reduce forward CO, further aggravating the patient's abnormal hemodynamics.

Aortic Aneurysm or Aortic Wall Disease

Movement of an IAB may jeopardize the integrity of the aortic wall in a patient with either of these conditions. Rupture of the aortic wall must be avoided.

Relative

Atherosclerosis

In some patients with severe atherosclerosis, the femoral arteries may be sufficiently plaque-filled and tortuous to prevent placement of the balloon.

End-stage Disease

Use of IABP may not be justified in some patients with late-stage terminal illness. This is an aggressive and invasive procedure and should be used only if the patient will derive significant clinical benefit.

Potential Complications

As with any invasive procedure, there are risks associated with IABP use. Potential complications arising from the use of IABP include the following:

Limb ischemia may result from obstruction caused by the presence or improper position of the catheter.

Aortic wall damage may be caused by stripping of the endothelial surface, improper placement of the catheter or unsuspected aortic wall disease.

Thrombosis can occur around the insertion site, on the aortic intima or on the catheter, if it is left dormant in the aorta.

Embolus formation may occur from the beginning of insertion to the post-removal phase. Materials known to embolize include thrombi, plaque, gas and air.

Infection may result when a debilitated patient is exposed to nosocomial organisms in the critical care setting.

Thrombocytopenia may be caused by the presence of the balloon, especially if the balloon totally occludes the aorta during inflation.

IAB Rupture and/or Entrapment If calcified plaque is present in the aorta around the area of the IAB, repeated contact with plaque may cause a loss of IAB membrane integrity. This may result in blood in the catheter or in prolonged exposure, clot in the IAB membrane. This may make IAB removal difficult. If blood is present or a leak is suspected, extreme caution must be exercised during IAB removal. Surgical removal should be considered.

Bleeding may occur at the IAB insertion site. If anticoagulation (ACT or aPTT), a higher risk of bleeding complications may be noted.

Function of the A*CAT*®1

The A*CAT*®1 IABP System is an advanced microprocessor based system designed for in hospital and transport applications. The A*CAT*®1 is compact, lightweight and can run with full operational capacity for a minimum of 120/240 minutes on battery power.

Precise IAB inflation and deflation is maintained by continuously monitoring the patient's current physiological data. The A*CAT*®1 can interface with most monitors, accept inputs from patient cables and transducers and the A*CAT*®1 is designed to save you time by automating many of the system's operating functions.

The A*CAT*®1 automatically:

- Selects start-up operating parameters that are appropriate for initiating counterpulsation
- Purges the pneumatic system for rapid initiation of IABP
- Removes water from the pneumatic tubing without interrupting pumping
- Refills the IAB line without interrupting pumping
- Adjusts timing for most variations in heart rate and arrhythmias
- Displays operation on a color LCD (Liquid Crystal Display) and alerts you to potential problems
- Shuts down the pump if a malfunction occurs
- Switches from AC to battery power when needed
- Continuously maintains adequate ECG size for reliable/consistent triggers.

These automated operating features make IABP initiation rapid and simple. You can then focus on optimizing IABP support to the patient. Using the system's controls, you can:

- select the sources of the ECG/AP
- zero and/or calibrate the transducer
- choose from seven trigger modes
- select the assist ratio for your patient
- set balloon inflation volume
- adjust balloon inflation and deflation timing
- define recorder settings
- use cursor to assess patient and pump parameters
- turn alarms on/off
- obtain function specific or startup help
- set up system clock

- show operational status of pump
- review hemodynamic calculations
- set audio level of alarms and keystrokes

You can easily monitor the system's operation and the patient's hemodynamic status by viewing the A*CAT*®1 high-resolution color LCD. This LCD continuously displays up to three waveforms, as well as the patient's hemodynamic data and relevant operating information. The A*CAT*®1 is equipped with a two channel annotating strip chart recorder for printing these waveforms and hemodynamic data.

Installation Procedures

After the A*CAT*®1 IABP System is delivered to your hospital or purchasing facility, an Arrow International Field Engineer will prepare the A*CAT*®1 for operation and thoroughly check its operational readiness. You must ensure that you have fulfilled certain pre-installation requirements.

This chapter outlines your pre-installation responsibilities and the installation procedures to be performed by Arrow International.

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Service Installation 2-4
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Pre-installation Requirements

As the user of the A*CAT*®1 IABP System, it is your responsibility to ensure that the following pre-installation requirements have been fulfilled prior to the system installation:

1. Make sure that the AC power source available to the installation site is properly grounded. The A*CAT*®1 will operate on 90-264 volt and 50/60 Hz.

WARNING – ELECTRIC SHOCK HAZARD

An electric shock hazard may exist with this system. Always operate the A*CAT*®1 from a 3-wire hospital-grade AC electrical system with a separate ground. **Do not** remove the round grounding pin from the system's plug. **Do not** use a 3-wire to 2-wire adapter to avoid the system's ground. Do not place fluids in the storage compartments on top of the A*CAT*®1.

WARNING

The biomedical engineering department or other qualified person should verify the integrity of the AC power system ground. In addition, the ground should be checked periodically.

If you are not certain that your power source is active and properly grounded, call the biomedical engineering department, hospital electrician or other qualified person.

2. ECG patient electrodes and pressure transducers are not supplied with the A*CAT*®1 IABP System. Make sure that they are available at the installation site.
3. Confirm that replacement supplies of USP helium and recording chart paper are available. (See Section 8.2 for ordering information.)

WARNING

The A*CAT*®1 IABP System requires a trained operator who has read and understands all sections of this manual prior to using the A*CAT*®1 IABP System. Only medical personnel trained in the use of IABP devices and acting under a physician's orders should operate this system.

4. The A*CAT*®1 should be operated by educated personnel only. Make sure that you have allocated adequate education time for potential users.

Arrow International, Inc. clinical specialists are willing to provide your staff with Basic or Advanced Education, according to your institution's requirements. Arrow provides a 24-hour Support Line for questions regarding A*CAT*®1 and other Arrow IABP operational and troubleshooting issues and may be accessed by calling:

1-800-447-6961 (U.S.A. & Canada)
or 1-617-389-8628 (outside the U.S.A. & Canada)

General product information may be requested from your local sales representative or distributor, or by calling:

1-800-523-8446 (U.S.A. & Canada)
or 1-610-378-0131 (outside the U.S.A. & Canada)

Service Installation

To insure that your A*CAT*®1 IABP System is properly installed and operational, an Arrow International representative will:

1. Open the packaging boxes/crates and verify its contents.

   You should receive the A*CAT*®1 console and an accessory kit containing:

   - Operations manual
   - Two fuses (5 Amp)
   - One Phono-to-Phono Cable
   - One Phono-to-Nicolay Cable
   - One 3-Lead ECG Patient Cable (5-Lead ECG Cable is optional. See section 8.2 for ordering information)
   - One box of recorder paper
   - Four canisters of helium (one case)
   - Three helium washers
   - Console bracket for IV pole

   You should also receive any optional accessories that you ordered with the A*CAT*®1.

2. Confirm that the A*CAT*®1 is free from shipping damage.
3. Install a new 500 psi disposable canister of USP helium (or 2000 psi refillable/ disposable tank). The helium tank is located behind left rear door on the main unit.

Note: The helium connection accepts a standard helium tank yoke assembly. A special adapter is provided if the 500 psi disposable tank is to be used. Place the adapter into the helium regulator assembly and tighten. The 500 psi disposable tank may now be installed. A helium washer must be installed between the adapter and the yoke for a leakproof seal.

4. Switch on the DC circuit breaker.

   The DC circuit breaker was switched off at the factory to prevent damage to the A*CAT*®1 during shipping. The DC circuit breaker is located in the top right of helium storage compartment.

5. Switch ON the A*CAT*®1 and check to make sure that the system's displays, indicators, controls, alarms, strip chart recorder, built-in battery and pneumatic drive module function properly.

AC Power

The A*CAT*®1 is equipped with a power entry module located at the bottom center of the I/O panel. The power entry module utilizes an IEC 320 inlet which features a detachable power cord, a power cord retaining clamp and a fuse drawer with two AC fuses which fuses both sides of the AC power line. Both fuses are required for normal operation. The A*CAT*®1 is shipped with the AC fuses already installed.

The power cord can be removed from the power entry module by unlatching the cord retaining clamp and pulling the cord out. The power cord can be installed into the power entry module by inserting power cord connector firmly into the inlet and securing the cord by snapping the cord retaining clamp over the cord.

Just below the Balloon Connector, there are two lights. A green light labeled POWER INDICATOR, when lit, indicates that the AC power cord of the A*CAT*®1 is plugged into an active AC power source. A yellow light labeled BATTERY CHARGED, when lit, indicates the battery is at least 80% charged.

The A*CAT*®1 is also equipped with an equipotentiality connector located just under the A*CAT*®1 on the right side.

Time Meter

The time meter is located in the lower left hand corner of the helium storage compartment. This storage compartment is located on the left rear of the main console. The power switch of the A*CAT*®1 must be switched ON in order for the time meter to display the total running time (in hours) of the A*CAT*®1.

Chapter 1 outlined the A*CAT*®1 and IABP indications. This chapter describes the functions of the A*CAT*®1 in more detail. Understanding the fundamentals of how the A*CAT*®1 works will enable you to operate and maintain the A*CAT*®1 efficiently. It is important that you read this chapter before attempting the operating, calibration, maintenance and troubleshooting procedures described in Chapters 5, 6, 8 and 9.

The first section in this chapter describes the configuration of the A*CAT*®1. The next two sections outline the mechanics of how the A*CAT*®1 works: the input and output connections that provide the signals necessary for operation (Section 3.2), and the function keys that allow you to select the operating parameters to optimize patient IABP support (Section 3.3). Finally, the chapter concludes with a discussion of the applications of these functions.

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Overview of the A*CAT*®1

The A*CAT*®1 IABP System utilizes advanced computer technology to maintain precise IAB inflation and deflation timing and triggering based on current physiological data from the patient. The system consists of two components: the pump control/display module and the pneumatic drive module with attached wheels for easy transport. An eight foot (2.5m) communication cable connects the pump control module to the pneumatic drive module (an optional 14 foot (4.1m) communications cable is available). The exterior of the A*CAT*®1 is constructed of urethane for reduced weight and improved durability during transport. To allow you to maximize the amount of working space during operation (especially during transport), the pump control/display module can be removed for optimum convenience.

Figure 3.1: The ACAT®1 *IABP System Configuration*

A*CAT*®1 Control Module

The A*CAT*®1 has a detachable control/display module, housing the LCD that shows all of the information you will monitor during pump operation and the function control keypad. The LCD shows three waveforms, each in a different color for easy identification and interpretation:

- Calibrated ECG trace (green, superimposed with white during assist intervals)
- Calibrated Arterial Pressure waveform (red, superimposed with white on UNASSISTED beats)
- Calibrated Balloon Pressure waveform (blue)

The blue horizontal scale at the bottom of the LCD shows the inflation/deflation range. This range is 0% to 120% of the R-R interval for all trigger modes. The distance between vertical lines represents 10% of the R-R or AP interval. An expanding green or red bar indicates the inflation and deflation set points. This bar changes to red during Arterial Pressure triggering. The bar changes to yellow if deflation timing is set beyond 100% (100% to 120% only). The patient's physiological data is displayed in white alphanumeric characters.

This data, displayed every beat, is calculated on a beat-to-beat basis. Heart Rate is averaged over four beats. In addition, a heart-shaped symbol flashes each time the system detects a trigger point. Physiological data that is displayed includes:

- HR (Heart Rate, in BPM)
- PSP (Peak Systolic Pressure, in mmHg)
- PDP (Peak Diastolic Pressure, in mmHg)
- EDP (End-Diastolic Pressure, in mmHg)
- MAP (Mean Arterial Pressure, in mmHg)
- Optional - BPW plateau pressure at end of inflation in mmHg

Operating information is also displayed in alphanumeric characters on the LCD. This information includes:

- Balloon Volume (that has been selected to be delivered)
- HE (remaining helium pressure in the tank, bargraph display in PSI)
- ALARM STATUS (on or off)
- Trigger Signal (flashing heart symbol and white highlights on green ECG trace)
- Diagnostics (alphanumeric messages)
- EGC Lead
- Arterial Pressure/Balloon Pressure Waveform Scales
- Cursor (magenta)

The *ACAT®*1 LCD display layout has been organized to provide you easy identification of information available on the LCD. The LCD is divided into areas where specific information will be displayed. Several areas may have more than one display characteristic while other areas are dedicated to specific waveforms or information.

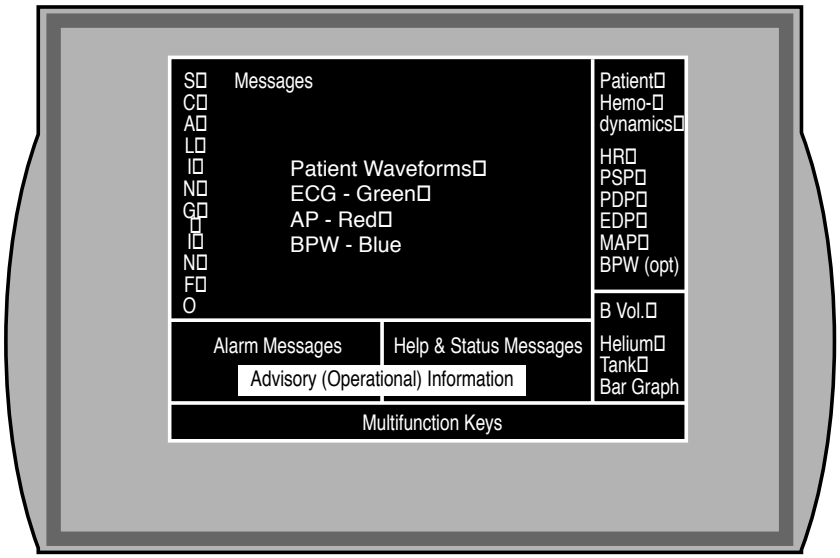


Figure 3.2: Screen area definitions

Around the LCD is the control function keypad. These control keys allow you to select all operating functions needed to run the *ACAT®*1. The control keys are labeled individually with their corresponding function. In addition, the power switch is located on the front of the console (shown in Figure 3.4). The operating functions of the displays and control keys are explained in detail in Sections 3.3 and 3.4. The control keys are grouped into the following categories:

- ECG Source Select - ECG Skin /Monitor
- AP Source Select - Transducer /Monitor
- Cursor
- Inflate/Deflate
- Pump Status
- Alarms
- Recorder
- Freeze Display
- Balloon Volume
- Assist Ratios
- Help/Home
- Trigger Mode
- Multi-Function Keys

Seven additional multi-function keys are located under the LCD display and correspond to the operation indicated directly above the key on the LCD.

The multi-function key legends change in response to certain operating key presses. These include:

- ECG Source select (ECG Lead Select)
- AP Source Select (zero/calibration/AP Scale)
- Alarms OFF (select time for alarms to be disabled)
- Balloon Volume (Volume Controls)
- Internal Trigger (Rate Selection)
- HOME

These keys will automatically return to the normal functions after 30 seconds, or immediately when the HOME key is pressed. The currently selected function is highlighted in reverse video.

The control/display module is mounted on a bracket and connected to the pneumatic drive module by an eight foot (2.5m) cord. The control module can be fully rotated 360°, on the base, raised upright to any position desired, or detached for placement on an IV pole display mount.

To rotate or change the viewing angle of the control module:

1. Press the blue button located on the rear of the pneumatic unit. The screen will rotate to any position and/or may be locked in 4 positions (90 degree intervals).

To raise or lower the control module:

1. To raise the control module press the blue button on the control module handle. Raise the display to the desired height. Release the button to lock control head at desired height.
2. To lower control module press the blue button and push the handle down to desired position. Release button to lock.

To detach/attach the control module from the IABP drive module:

1. Reach behind the control module to the central section.
2. Pull up the upper blue handle by squeezing it upwards.
3. Lift the module straight up to clear the mounting bracket.
4. To reattach control module, place it over the locating pins and push down until a click is heard, indicating it is locked in place.

To tilt the control module up or down:

1. Lift up on the lower blue handle on the back of the control module.
2. Move to the desired position and release the handle.

To allow for viewing of the LCD during transport, position the control module so that it lays flat and face up over the top of the A*CAT*®1.

Figure 3.3: The ACAT®1 LCD and Control Function Keypad

WARNING

Do not transport the ACAT®1 with the control module in the upright position. The control module must be positioned down, flat to the pump module prior to transport, or the control module may be removed from the pump and carried.

To place the control/display module on the IV Pole Display Mount:

1. Detach the control module from the IABP drive module.
2. Slide the control/display module down over the mounting bracket on the IV Pole Mount.
3. The control/display module is secure when a click is felt.

To place the control/display module on the IABP drive module:

1. Position the mounting bracket on the IABP drive module to any position.
2. Slide the control/display module down over the mounting bracket on the IABP drive module until it clicks into place.

Patient Connections

The front of the console contains the balloon connector and all of the input and output connections required to receive the signals that allow the control system to analyze the patient's status.

Figure 3.4: The ACAT®1 Connector Panel and Power Switch

Storage Compartment

The top panel contains a compartment for storage of paper and other small accessories.

Figure 3.5: Top Panel Storage Compartment

Pneumatic Drive Module

The pneumatic drive module contains the pumping system needed for IABP operation. A 500 psi disposable or 2000 psi refillable/disposable helium tank is housed in a compartment at the left rear of the pneumatic drive unit. The front of the module contains the power switch, balloon connector, AC indicator lamp and a battery charge lamp, all of the input and output connections required to receive the signals that allow the control unit to analyze the patient's status. Also a flash card receptacle, modem connection and RS 232 connector are available. The pneumatic drive unit has four 360 degree swivel wheels which can be locked into position by depressing the pedal, located in the center of each wheel. This is designed to minimize IABP configuration for transport.

System Battery

The A*CAT*®1 battery system is located inside the pneumatic drive module and the circuit breaker is located in the helium storage compartment. The A*CAT*®1 battery system allows you to use the system with full operational capabilities for a minimum of 120 minutes in case of AC power failure. An optional battery can be added to the unit to increase battery operating time to a minimum of 240 minutes. The system automatically switches to battery power when AC power is removed. Warning messages appear when the DC circuit breaker is off, and when 20, 10 and 5 minutes of battery power remain. The batteries recharge automatically whenever the system is connected to AC power. **Recharging completely discharged batteries requires about eight hours, but 80% of the batteries' charge is restored within four hours.** A yellow indicator light is located on the front panel to show when 80% battery charge is available. Protective circuitry prevents overcharging. The green light labeled "Power Indicator" on the A*CAT*®1 front panel will illuminate when the A*CAT*®1 is plugged into AC power. More information regarding the system batteries, how to test the batteries, and how to replace the batteries is found in the Maintenance Section of this manual, section 8.1.

Strip Chart Recorder

A strip chart recorder is located on the front of the console. This dual-channel annotating recorder uses 50mm-wide thermally sensitive paper and will record up to two waveforms simultaneously: ECG, AP and Balloon Pressure. Bars across the top of the recorder strip show assist intervals. The patient's hemodynamic data is also recorded, along with current alarm messages, IAB volume, assist ratio, ECG trigger mode, assist markers, ECG lead, AP/BPW scale, date and time. The recorder can be turned on or off at any time during operation. Certain alarms (discussed further in Section 3.3) automatically trigger the strip chart recorder to print approximately the last seven seconds of the Balloon Pressure and AP waveforms and the patient hemodynamic data, current alarm message trigger mode, assist ratio, balloon volume, ECG lead, timing settings, date and time. The recorder may be pre-programmed to automatically print approximately seven seconds of waveforms and data at 2 min., 15 min., 30 min., 60 min., 2 hr. or 4 hr. intervals.

Figure 3.6: The Strip Chart Recorder

Input and Output Connections

The A*CAT*®1 will interface with most bedside monitors and can also receive inputs directly from the patient. All input and output connectors are located on the front of the pneumatic drive unit. There are two EGG input connectors (skin, High Level monitor), two arterial pressure input connectors (transducer and High Level monitor). Three Patient Signal outputs are available for ECG, AP and BPW. The Assist Interval output provides a signal output to a simulator for use during training or testing. Pump information is available via a flashcard, modem or RS232.

Figure 3.7: Input and Output Connectors

Signal INPUT and signal OUTPUT connectors are designated for exclusive connection to equipment as specified in the documents accompanying such equipment (i.e. such equipment needs to be connected to the common protective earth of the system (if class I) or to a separation device). With all the equipment connected, the system needs to be in compliance with leakage currents requirement per IEC 601-1-1 (see also Electrical Safety Test procedure in the A*CAT*®1 Service Manual).

Input Connections

Input connectors are used to provide up to two signals to the A*CAT*®1 System:

- an ECG signal from an ECG monitor or directly from the patient
- an AP signal from an AP monitor or transducer

The A*CAT*®1 should be connected to both ECG and AP input sources to allow the control system to provide several ECG and AP trigger modes, and to display the patient's hemodynamic status. When these connections are made, ECG and AP waveforms are displayed on the LCD, allowing you to monitor the effects of counterpulsation. Connecting the A*CAT*®1 to properly calibrated ECG and AP monitors is generally the easiest and quickest way to initiate IABP operation.

There are two types of input connectors. "High-level monitor" inputs are phono connectors that receive signals from monitors. "Low-level" inputs receive signals from ECG patient cables and pressure transducers. **Direct ECG/AP connection from the patient to the A*CAT*®1 is preferred.** Cables are available from Arrow International. See Section 8.2 for ordering information.

Note: *It is important that the monitor output signals for ECG and AP are compatible with the* A*CAT*®1. *Some monitors require special modules to output this information. Be sure you have the correct equipment available.*

Input Connectors

ECG MON input jack (1/4" phono) green ring	Phono jack for accepting ECG signals (±6 volts DC maximum) from a remote monitor. Input to this jack is displayed on the green ECG (top) line of the A*CAT*®1 waveform display.
ART PRESS input jack (1/4" phono) orange ring	Phono jack accepts signals (up to ±6 volts DC, 100mmHg/volt) from a remote Arterial Pressure monitor. Input to this jack is displayed on the red Arterial Pressure (second) line of the A*CAT*®1 waveform display. Output of the remote monitor must be calibrated at 100mmHg/volt.
ECG patient electrode cable connection via ECG cable or Phono-Nicolay cable	Nicolay connector for patient ECG cable. Input to this connector is amplified by the A*CAT*®1 and displayed on the green ECG (top) line of the A*CAT*®1 waveform display.
ARTERIAL PRESSURE transducer cable connection	Nicolay connector for an Arterial Pressure Transducer (use only Spectramed transducers or their electrical equivalents, i.e. 50 µV/V/cm Hg). Input to this connector is amplified by the A*CAT*®1 and is displayed on the red Arterial Pressure (second) line of the A*CAT*®1 waveform display.

Output Connections

Output connectors allow you to output signals for display on an external monitor ("low-level" input signals must be used to do this) or use with an interactive simulator.

Output Connectors	
ECG output jack (green ring)	Phono jack provides signal for displaying or recording the A*CAT*®1 ECG trace on an external monitor. (Maximum output: ±6 volts DC.)
ART PRESS output jack (orange ring)	Phono jack provides signal for displaying or recording the A*CAT*®1 Arterial Pressure trace on an external monitor. Output is calibrated at 100mmHg/volt.
BLN PRESS output jack (blue ring)	Phono jack provides signal for displaying or recording the A*CAT*®1 balloon pressure trace on an external monitor. Output is calibrated at 100mmHg/volt.
ASST INT (yellow ring)	Phono jack provides a signal for use with an interactive simulator (used for training or testing purposes).

Data Connections	
Flash Card	PCMCIA standard flash card will provide selected (alternative) startup settings and provide storage for QA log.
Modem	Will provide real time output of all information to remote computer for monitoring or troubleshooting assistance.
RS 232	DB-9 connector provides a serial transmission of hemodynamic values, current alarms time and date.

Balloon Connection

The input labeled BALLOON connects the IAB's helium supply line to the A*CAT*®1. The A*CAT*®1 accepts Arrow International's electronically-coded balloon connectors, which automatically set pumping volume to match the balloon's maximum volume capacity. This connector also limits the amount of helium which can be delivered to the IAB to the IAB's maximum volume.

Function Control Keys

The A*CAT*®1 keypad includes twenty-three (23) operation control keys and seven (7) multi-function keys. The following pages describe each section of the control keypad and individual key functions. The function control keypad display is pictured in Figure 3.9. Control keys and selections are explained in the order of their appearance on the control module from top to bottom. Preset selections are bracketed in this text for clarity.

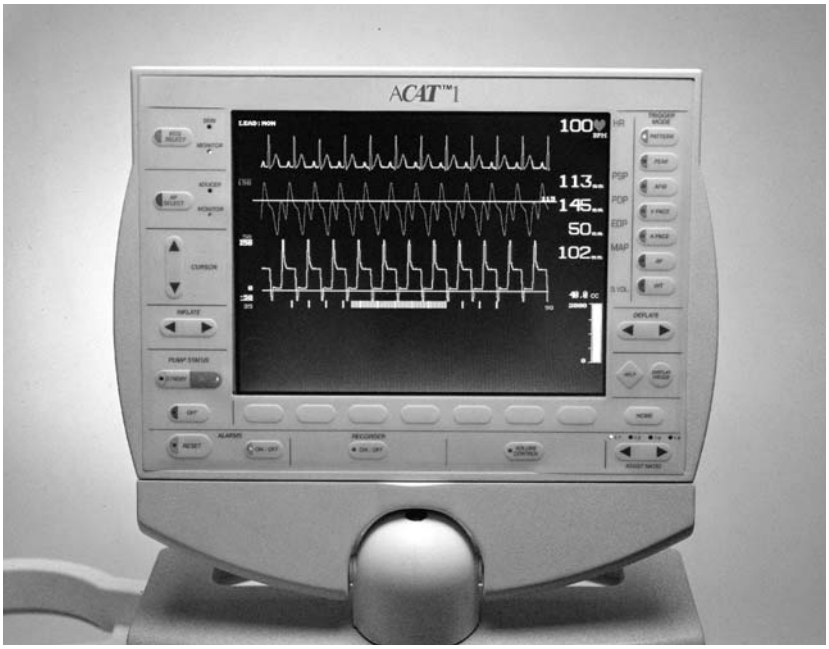
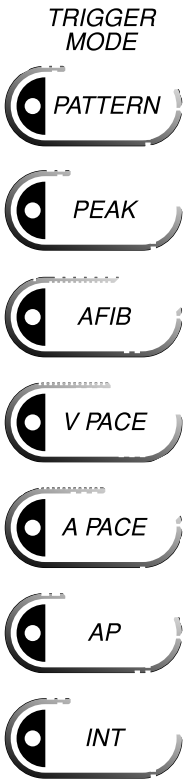


Figure 3.8: Front panel of control/display module.

Inflate/Deflate Control Keys

Inflate / Deflate Control Keys	
INFLATE	Adjusts the inflation point (seen as a green or red bar at the bottom of the LCD); inflation occurs later when the right arrow is depressed and earlier when the left arrow is depressed; allows operator to optimize timing by monitoring the hemodynamic changes produced on the AP waveform.
DEFLATE	Adjusts the deflation point (seen as a green or red bar at the bottom of the LCD); deflation occurs later when the right arrow is depressed and earlier when the left arrow is depressed; allows operator to optimize timing by monitoring the hemodynamic changes produced on the AP waveform. Note: Actual numeric values for Inflate and Deflate settings are given under the timing bar positions. These represent the percentage of R-R or Arterial to Arterial waveform in which IAB inflation occurs. Timing bar changes to yellow when deflation >100%.

Trigger Control Keys



The A*CAT*®1 is equipped with seven trigger modes, located to the right of the LCD. When the unit is first turned on, the trigger mode is preset to ECG Pattern trigger. The trigger mode is easily changed by pressing the key that corresponds to the desired trigger mode. A complete description of the trigger modes are described on the next page and later in the chapter. Trigger mode may be changed while pumping. Each trigger mode has memory of timing settings specific to that trigger selection (PATTERN and PEAK share a common memory). This reduces the need to adjust timing when the trigger selection is changed.

Trigger Control Key Functions	
Control Key	**Description**
[PATTERN]	Uses the ECG QR slope, amplitude and width (25-135ms) to define triggers; the most precise ECG trigger, PATTERN is frequently used for patients with routine QRS complexes; may be used with demand pacing.
PEAK	Uses the ECG QR slope and amplitude to define triggers; generally used for patients with wide QRS complexes; may be used with demand pacing and may be preferred for HR > 140 bpm.
AFIB	Defines inflation triggers based on PEAK mode, and triggers deflation when the slope of the R-wave begins to rise; generally used for patients with atrial fibrillation, irregular rhythms and tachyarrhythmias (operator cannot adjust deflation point in this mode). Also selected for Real Time Timing.
VPACE	Uses ventricular pacing spike to define triggers; may only be used for patients with 100% Ventricular or Atrio-Ventricular paced ECG rhythms (A/V interval must be set at 250ms or less).
APACE	Uses the atrial pacing spike to define triggers; may only be used for patients with 100% Atrial pacing.
AP	Uses rising slope of AP waveform (with blanking for the balloon) to define triggers; may be used when changing electrodes; for patients with 100% pacing: or when interference prevents use of ECG triggers; this mode should not be used for patients with A Fib or tachyarrhythmias.
INT	Rate is set by the operator and external patient signals are ignored; this selection automatically changes RATIO to 1:1. **To engage the internal trigger, the key must be selected and pressed a second time for confirmation.** Preset Rate is 80 BPM. The multi-function keys change when internal trigger is selected to allow internal rate to be changed.

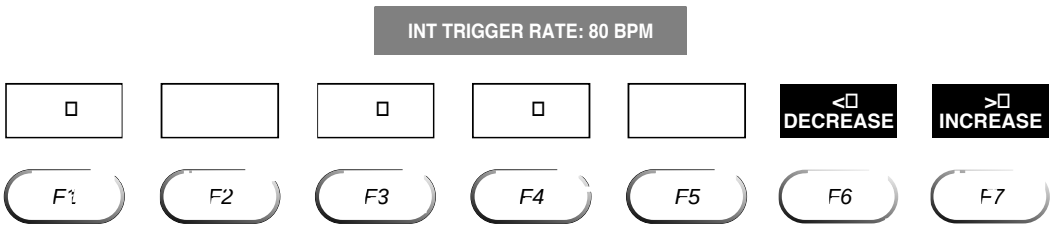


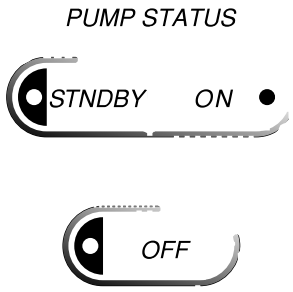
Figure 3.9: Adjustment of Internal Trigger Rate via the multi-function keys.

WARNING

The INTERNAL trigger mode should be used only if the patient has no myocardial activity and/or ventricular ejection. You must press the INT control key in the TRIGGER MODE section of the keypad twice if you wish to operate the ACAT®1 IABP in the INTERNAL trigger mode. An audible alarm will sound to alert you that an ECG is present when INTERNAL is selected. A warning message "INTERNAL" is displayed continuously above the ECG trace when INT is selected.

Note: ***If the power is turned off, the trigger mode is reset to default [PATTERN].***

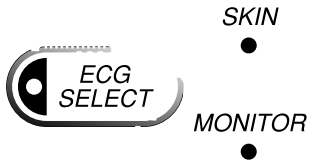
Pump Status



Pump Status Control Key Functions

Control Key	Description
ON	Fills the pneumatic system with helium to 2.5mmHg, and starts pumping; if pressed before PUMP STNDBY, pumping starts after one purge cycle.
STNDBY	If pump is on, immediately stops pumping but does not vent the pneumatic system; if pump is off, completes a four beat purge cycle and pressurizes the pneumatic system to 2.5mmHg; four alarms (described later in this section) cause the pump to go into standby mode.
OFF	Immediately stops pumping, deflates the balloon and vents the pneumatic system to atmosphere; six alarms (described later in this section) automatically stop the pump.

Signal Input Selection



ECG Signal Source

The ECG Signal Source Selection allows you to select the source of the ECG signal from either the ECG skin leads or from the bedside monitor via a Phono-to-Nicolay cable (low level input). When using the Phono-to-Nicolay cable, Lead II must be selected. An LED light indicates the current selection.

When the ECG Signal Source is in ECG Skin and the SELECT key is pressed, the multi-function keys will change to reveal the leads which are available to the pump. The number of leads available will depend on whether a 3 or 5 lead direct ECG cable is used. When either of these cables is connected to the A*CAT*®1, the type of cable and therefore ECG leads available is *automatically* recognized. Therefore only leads I, II and III are available with the 3 lead cable, while leads I, II, III, AVR, AVL, AVF and V are available from the 5 lead cable.

The default lead is lead II in both cases and is displayed in the upper left corner of the LCD display. To change the ECG lead, press the multi-function key under the desired lead. The reverse video highlight will indicate your new selection and the lead selection displayed on the LCD will display the new lead.

If you wish to change to the direct monitor input, using the Phono-to-Phono cable, simply press the SELECT key a second time and the LED will indicate that the selection is now MONITOR. The lead displayed on the A*CAT*®1 will be the same as the bedside monitor.

Manual and Automatic Gain

Autogain of the ECG Signal functions continuously so there is normally no need to adjust the ECG size. However, a manual gain override is available if needed.

When a 3-lead ECG cable is used, the AUTO/MAN functions appear on the multifunction keys after Lead III.

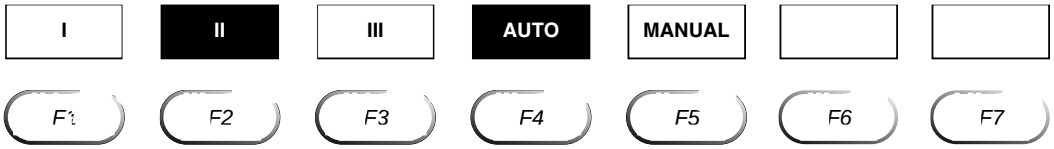


Figure 3.10: ECG Lead Selection (3 lead cable) via ECG Select Key and Multifunction Keys

The preset parameters are Lead II and AUTO.

When MANUAL GAIN is pressed, the following appears:

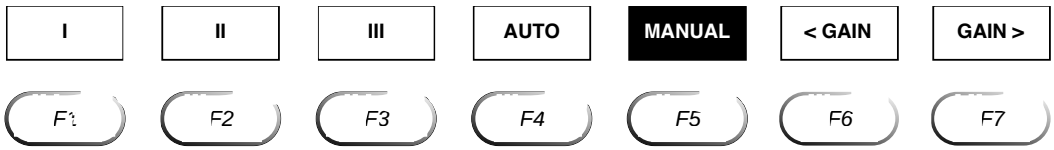


Figure 3.11: ECG Lead Selection with Manual Gain Control

Gain can be adjusted via the < DECREASE and > INCREASE keys.

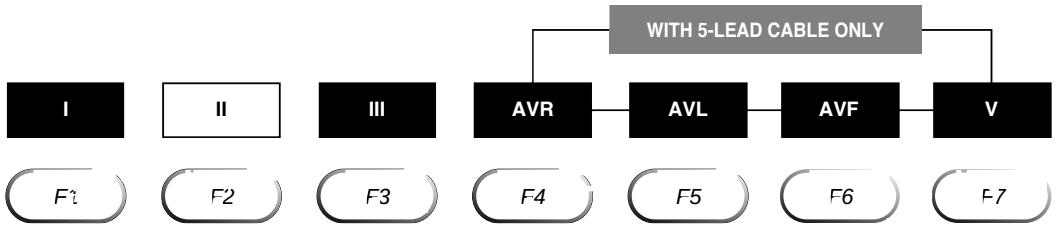
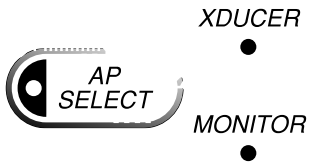


Figure 3.12: ECG Lead Selection via multi-function keys

AP Signal Source Select



The AP SELECT key allows you to select the input source used by the A*CAT*®1 for the arterial pressure displayed on the second channel of the LCD. You may choose either the direct transducer from the orange Nicolay connector or the High Level monitor input.

The LED will indicate which source is currently being used by the A*CAT*®1. When AP Select is pressed the multi-function keys will display options to change AP Scale, Zero and Calibrate the selected signal source. To change the source of the AP signal, press the AP Select key until the desired AP signal LED is lit.

NOTE: The multi-function keys display the same options for AP Scale, Zero and calibration functions.

To zero the transducer:

1. Select the desired AP source.
2. Open transducer to air.
3. Press ZERO.
   Note: message AP ZERO'D
4. Close transducer to air.

To adjust AP scale:

1. If multifunction keys have reset off the display, press AP SELECT.
2. *OR*–Press AP SCALING and select desired scale.

To calibrate the AP Transducer, see section 6.1.

NOTE: Mercury manometer calibration is not necessary except when a reusable transducer is employed. See section 6.1 for a detailed explanation of calibration.

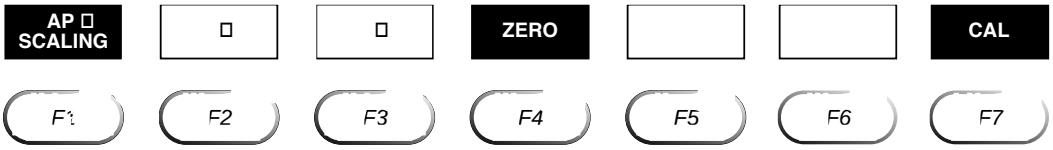


Figure 3.13: AP Scaling, Transducer Zero and Calibration Functions

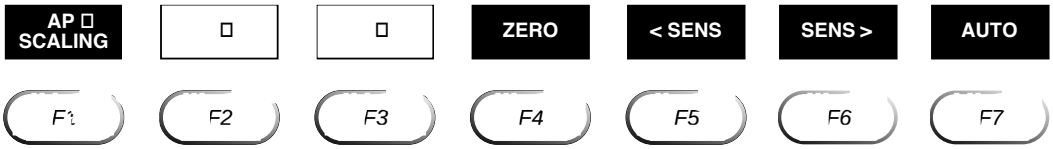
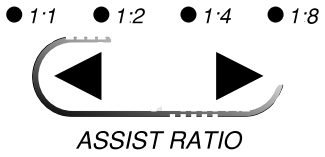


Figure 3.14: AP Sensitivity when CAL is pressed.

Assist Ratio



The ASSIST RATIO control keys are used to select the frequency of IABP assist the patient will receive. Counterpulsation is usually initiated in a 1:2, or every other cardiac cycle, setting, hence, this selection is preset at powerup. Using the left or right arrow keys you can choose your selection. The ASSIST RATIO can be selected in either direction. The LED for the selected ASSIST RATIO will be illuminated.

Assist Ratio Control Keys

Selection	Description
1:1	Initiates one inflation-deflation cycle for each cardiac cycle; generally used after timing has been optimized.
[1:2]	Initiates one inflation-deflation cycle for every second cardiac cycle; generally used to initiate counterpulsation and optimize timing, and to wean patient from IABP support.
1:4	Initiates one inflation-deflation cycle for every fourth cardiac cycle; generally used to wean patient from IABP support.
1:8	Initiates one inflation-deflation cycle for every eighth cardiac cycle; generally used to wean patient from IABP support.

Balloon Volume

The BALLOON VOLUME function key will allow the balloon volume to be changed from the present setting. Press the VOLUME key to access volume controls. When the VOLUME key is pressed, the multi-function key will change to the following:

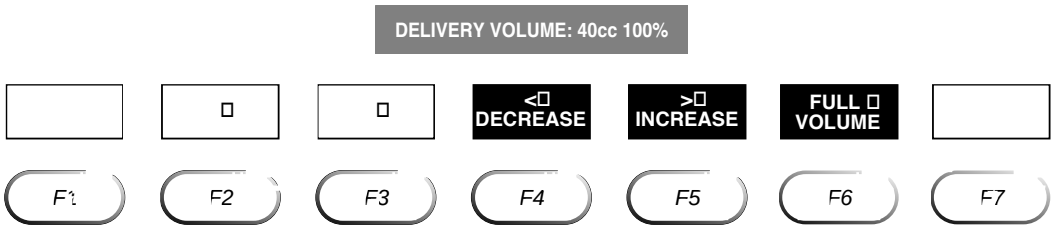


Figure 3.15:Initial display of volume change.

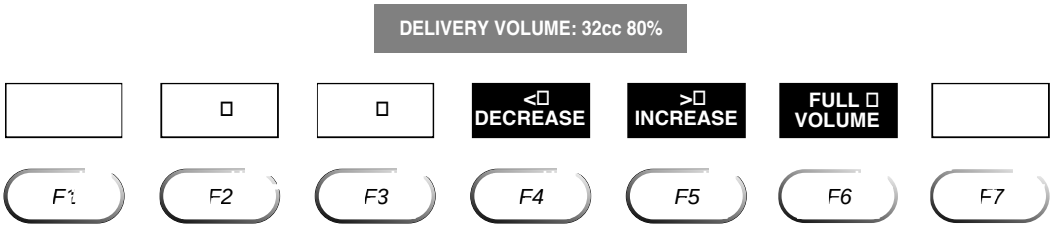


Figure 3.16: Example of IAB volume change to less than full volume.

Change Volume

1. Press PUMP OFF key.
2. Press VOLUME CONTROL key.
3. Increase or decrease the balloon volume to the desired volume by pressing either the INCREASE or DECREASE multi-function key.
4. Press PUMP ON to resume pumping at new volume setting.

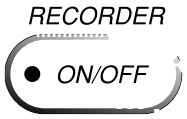
Return to Full Volume

1. Press PUMP OFF key.
2. Press VOLUME CONTROL key.
3. Press FULL VOLUME key.
4. Press PUMP ON to resume pumping.

NOTE: Volume cannot be adjusted above the maximum volume of the IAB connector.

CAUTION: Always use the proper IAB connector to insure safe and effective counterpulsation.

Recorder Control Keys



The *ACAT*®1 is equipped with an annotating strip chart recorder. You can start or stop a recording by pressing the Recorder ON/OFF key. Selection of recorded parameters is done by the use of the Recorder Setup in the multi-function key section.

Recorder Setup Control Key Functions

Control key	Description
RECORDER ON/OFF	Turns recorder on/off.

Alarm System

The ALARM control keys allow you to disable or enable A*CAT*®1 diagnostic alarms. Before describing the ALARM control keys further, the A*CAT*®1 diagnostic alarm system will be explained.

The A*CAT*®1 diagnostic alarm system continuously monitors operating conditions. The A*CAT*®1 is able to detect and alert you to 21 conditions that require a response. When an alarm condition occurs, the A*CAT*®1 displays an alarm message, including suggested corrective actions. Press the ALARM RESET control key to reset the audio tone. Possible causes and corrective actions are listed in Chapter 9, Troubleshooting. (If the alarm is not reset automatically, ALARM RESET must be pressed prior to re-initiating pumping. If multiple alarms have been issued, the ALARM RESET key must be pressed once for each alarm present.)

The 21 alarms are organized into three classes: Class 1, Automatic Response; Class 2, Automatic Response; Class 3, and Information Only. The six Class 1 (automatic response) alarms alert you to potentially serious conditions that require your immediate attention. Certain alarms have subcodes (System Error, Large Helium Leak, High Baseline, and High Pressure). These subcodes will be displayed on the LCD as a number in brackets. These subcodes are used only for engineering purposes and are not significant in the clinical environment.

WARNING

Alarms should be on at all times to insure safe operation. If alarms are suspended, the IABP should be continuously monitored by trained personnel. A warning message "ALARMS OFF" will be continuously displayed above the ECG trace when alarms are off.

Multiple Alarm Handling

Multiple alarm conditions can occur. Alarm handling by the A*CAT*®1 is based on a unique priority code assigned to each alarm. The highest priority alarm which occurs is always displayed first.

When multiple alarms occur, these alarms are stacked in the order of priority. To view each alarm condition, press the RESET key. Each subsequent alarm will be displayed in priority order with troubleshooting information. Continue to RESET the alarms until all alarms are cleared. When all alarms are cleared the RESET LED will be off.

NOTE: Alarms are listed by Class from highest to lowest priority in the following tables.

Class 1 (Automatic Response) Alarms	
SYSTEM ERROR	The A*CAT*®1 computer circuitry has malfunctioned.
POSSIBLE HELIUM LEAK	1. The A*CAT*®1 cannot autofill the pneumatic system to +2.5 mmHg within 8 beats. 2. The A*CAT*®1 attempts a second autofill within 1 minute. 3. The baseline falls below -10mmHg while pumping.
HIGH BALLOON PRESSURE	The pressure in the balloon line exceeds 250mmHg at the end of inflation for 3 consecutive cycles or for 6 out of the last 12 cycles.
HIGH BASELINE	The pressure in the balloon line exceeds 25mmHg while the balloon is deflated.
LARGE HELIUM LEAK DETECTED	The balloon pressure waveform plateau falls below 5mmHg immediately before the onset of deflation, the balloon pressure peak decreases by 50% within 5 beats, or the balloon inflated equilibrium pressure drops below 12% of inflation peak pressure within 5 beats.
PURGE FAILURE	The A*CAT*®1 cannot complete pneumatic purge sequence.

NOTE: Alarms are listed in order of priority from highest to lowest in each class.

The Class 1 Alarms cause the A*CAT*®1 to:

- stop pumping (PUMP OFF key illuminates)
- deflate the balloon
- open the vent valve
- initiate an audio alarm
- display an alarm message
- freeze the waveform display
- print approximately the last seven seconds of balloon and AP waveforms on the strip chart recorder
- automatic entry in QA log

The four Class 2 (Automatic Response) Alarms also require your immediate attention.

Class 2 (Automatic Response) Alarms	
STANDBY	Pump has been left in STANDBY for 3 minutes.
ECG TRIGGER LOSS	Eight seconds elapsed without a recognizable trigger point in the ECG waveform (occurs only in PATTERN, PEAK, A FIB, V PACER and A PACER trigger modes). NOTE: ECG Trigger Loss Alarm is extended to 30 seconds when alarms are off.
PRESSURE TRIGGERING LOSS	Eight seconds elapsed without a recognizable trigger point in the AP waveform (occurs only in ART PRESS trigger mode). NOTE: Pressure Triggering Loss Alarm is extended to 30 seconds when alarms are off.
ECG LEAD FAULT DETECTED	The A*CAT*®1 detects high electrical impedance in the ECG leads (usually caused by loose or broken patient leads).

The Class 2 Alarms cause the A*CAT*®1 to:

- stop pumping (PUMP STNDBY key illuminated, system not vented)
- deflate the balloon
- initiate an audio alarm
- display an alarm message
- automatic entry in QA log

If you do not respond to the automatic response alarms within 60 seconds by pressing ALARM RESET, another audio alarm will sound. The visual alarm message does not clear until you press ALARM RESET and PUMP STNDBY or PUMP ON (Class 1), or ALARM RESET and PUMP ON (Class 2). If the condition which caused a Class 2 alarm to occur resolves spontaneously, the alarm will reset automatically.

The eleven Class 3 (Information Only) Alarms alert you to less serious conditions. Class 3 Alarms initiate an audio alarm and cause a visual alarm message to be displayed on the LCD, and entry to QA log, but do not interrupt counterpulsation.

Class 3 (Information Only) Alarms

DRAIN FAILURE	The A*CAT*®1 was unable to complete a full drain cycle.
DEFLATION > 100%	Deflation is set to occur beyond 100% of the R-R interval (Timing bar turns yellow beyond 100%)
TIMING ERROR	Inflation and deflation points need to be adjusted (insufficient time to deflate the balloon before the next inflation cycle).
BATTERY INOPERATIVE	The A*CAT*®1 will not run in battery mode due to a faulty DC circuit breaker.
BATTERY LIFE LESS THAN 5 MINUTES	Less than 5 minutes of battery power remain before system battery operation shuts down.
BATTERY LIFE LESS THAN 10 MINUTES	Less than 10 minutes of battery power remain before system battery operation shuts down.
BATTERY LIFE LESS THAN 20 MINUTES	Less than 20 minutes of battery power remain before system battery operation shuts down.
SYSTEM RUNNING ON BATTERY	AC power was intentionally or accidentally disconnected and the A*CAT*®1 has automatically switched to battery power.
LOW HELIUM SUPPLY	The helium tank's pressure is less than 100psi (also occurs if the helium tank is not inserted correctly).
ECG DETECTED DURING INTERNAL TRIGGER	Patient may have regained electrical activity. Reevaluate trigger selected.
LOW BATTERY FOR STATIC RAM	The internal static ram battery on the CPU board needs to be replaced.

When the condition that caused a Class 2 or Class 3 Alarm is corrected, the audible alarm tone will reset automatically and if pumping status went to STNDBY due to alarm, pumping will resume automatically.

Alarm Control Keys

The ALARM control keys allow you to reset the audio alarm tone; allow you to disable the pneumatic alarms for a period of up to 60 minutes[2], or permanently if selected internally;and allow you to re-enable the alarm system when it is in the OFF mode. A symbol indicating that the alarms are off will be seen in the left corner of the display under the LEAD SELECT. The actual number of minutes remaining is also displayed. The alarms automatically resume when the number of minutes reaches 0 min. An ALARMS OFF message is continuously displayed on the top of the display above the ECG while the alarms are off.

The ALARMS OFF control key allows you to disable the A*CAT*®1 diagnostic alarms when you test and troubleshoot the system. The ALARMS OFF key disables all Class 1 alarms except SYSTEM ERROR. The alarms should be on during normal operation.
You can also adjust the volume of the audio alarm tone. When ALARMS OFF is pressed the multi-function keys show the selections for the number of minutes for alarms to be disabled. Current selection is highlighted in reverse video.

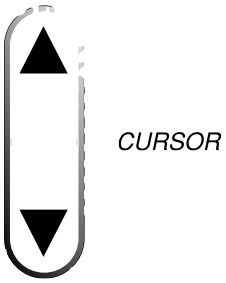
Figure 3.18: ALARMS OFF time (minutes) selections

Note: PERMANENT OFF is available only if an internal switch is selected. To disable alarms permanently, press PERMANENT OFF again to confirm. Alarm messages are displayed when alarms are off.

Alarm Control Keys

Selection	Description
OFF	Disables all Class 1 alarms except SYSTEM ERROR. Pressing the multi-function control key changes the disabled period by ten minutes, up to a maximum of 60 minutes (alarms are automatically restored after the disabled period has elapsed). **Note:** ***FLASHING LED ON ALARMS OFF CONTROL KEY INDICATES THAT THE ALARMS ARE DISABLED AND A SYMBOL IS DISPLAYED.***
[ON]	Restores normal alarm functions if alarms have been disabled.
RESET	Silences the audible alarm tone and clears the alarm message; if pumping was interrupted, the alarm message is not cleared until PUMP STNDBY or PUMP ON is pressed; if there is more than one alarm condition, one alarm message is cleared at a time. RESET must be pressed prior to reinitiating pumping for Class 1 alarms.

Cursor



The *ACAT*®1 has a horizontal cursor. This cursor will allow specific measurements of the Arterial Pressure Waveform or of the Balloon Pressure Waveform.

The cursor may be moved by pressing the 9 or (arrow key in the cursor section. The cursor moves in 2 or 3mmHg increments. The numerical value located at the point where the cursor intersects the waveform is seen at the right hand side of the waveform area for which the cursor is being used, on the cursor line.

The cursor may also be used when the waveform display is frozen. To freeze waveforms, press DISPLAY FREEZE and then use the cursor as described.

Help

The A*CAT*®1 IABP system has HELP incorporated for many of the pump functions. HELP is accessed via the HELP key on the Right side of the keypad. All HELP screens are displayed in the lower Right side of the LCD in WHITE text.

There are two kinds of HELP messages, general or setup HELP and key-specific HELP which may be used with a single function or multifunction key.

Most keys on the A*CAT*®1 will have key specific HELP text. Key specific HELP will be displayed when the user touches the HELP key and then touches the desired key within 10 seconds.

The following keys will have HELP text:

HELP (Initial Setup only)
ECG Select
AP Select
Timing Keys (All)
Cursor Keys
Recorder ON/OFF
Alarms ON/OFF
Balloon Volume
Multifunction Keys
Trigger Keys (ALL)

If HELP is pressed, Initial Setup HELP will be displayed or the message:

PRESS DESIRED KEY FOR HELP MESSAGE
OR PRESS HELP AGAIN TO CANCEL REQUEST

HELP Operations summary:

INITIAL SETUP: Touch HELP
KEY SPECIFIC HELP: Touch HELP then DESIRED KEY
MULTIFUNCTION HELP: Touch HOME, then HELP, then DESIRED KEY

To cancel HELP touch the HELP key while the message above is displayed. All HELP text and messages will be cleared from the display. NOTE: When HELP is activated BEFORE a key press, ONLY the HELP message will be displayed. The function of the key pressed will NOT be activated until the subsequent press of the same key that HELP is describing or on the press of any other key.

Help Key Operations and Text

The following is a summary of the HELP text which will be displayed with different key combinations. This table shows the keys presses and HELP message which will be displayed for that key.

KEY 1	KEY 2	KEY 3	HELP MESSAGE AND TEXT
HELP			1. Select ECG and AP signal source 2. Connect balloon 3. Select trigger mode and assist ratio 4. Adjust timing 5. Press Pump standby, Pump on.
HELP	ECG SELECT		ECG SELECT provides selection for LEAD, input source, gain mode and level. To change input source, press ECG SELECT again. To change lead press key under desired LEAD label. To switch gain mode press key under desired label. Use < and > keys to adjust manual gain.
HELP	AP SELECT		AP SELECT provides selection for source SCALE, ZERO and CAL. To change input source, press AP SELECT again. To change AP scale, press AP SCALING. To zero, open transducer to air and press ZERO. To CAL, input 100mmHg and adjust sensitivity.
HELP	CURSOR		Moves horizontal cursor on AP and BPW. Move cursor to desired assessment point. Value is displayed above cursor on the right hand side.

KEY 1	KEY 2	KEY 3	HELP MESSAGE AND TEXT
HELP	INFLATION TIMING		INFLATION TIMING: Set ASSIST RATIO to 1:2. Locate DN between PSP and PDP INFLATION: Set at, or just prior to DN, so that: PDP>PSP Check Deflation timing or set ASSIST RATIO to 1:1
HELP	DEFLATION TIMING		DEFLATION TIMING: Set ASSIST RATIO to 1:2. DEFLATION: Set deflation timing to: BAEDP < PAEDP & APSP < PSP Check Inflation timing or set ASSIST RATIO to 1:1
HELP	ALARMS ON/OFF		Turns alarms audio, recording, drain and refill on or off. To select alarm time off, press key under desired setting. Alarm messages will still be displayed. Time remaining for alarms off is displayed above the AP Scale. Press ON/OFF again to turn on alarms.
HELP	RECORDER ON/OFF		Starts and stops recorder. To change recorder settings press HOME and RECORDER SETUP
HELP	BALLOON VOLUME		Press pump OFF to change volume. Select INCREASE/ DECREASE until desired volume is displayed. Press FULL VOLUME to return to volume based on balloon connector.

KEY 1	KEY 2	KEY 3	HELP MESSAGE AND TEXT
HELP	PATTERN		PATTERN trigger mode Preset trigger; for normal QRS complex. Uses height, width and slope of positive or negative QRS complexes. Width must be between 25 and 135 mSec. Rejects pacer spikes.
HELP	PEAK		PEAK trigger mode For any type of QRS complex and changing QRS shapes. Uses height, slope only of positive or negative QRS complexes. May be preferred for HR > 140. Rejects pacer spikes.
HELP	AFIB		AFIB trigger mode For irregular cardiac rhythms. Uses height, slope only of positive or negative QRS complexes with REAL TIME (R-Wave) deflation. Rejects pacer spikes.
HELP	VPACE		VPACE trigger mode Uses V-pacer spikes to trigger, MUST BE 100% PACED. For V and AV sequential pacers. ECG SKIN cable connection recommended.
HELP	APACE		APACE trigger mode Uses A-pacer spikes to trigger, MUST BE 100% PACED. For Atrial pacers only. ECG SKIN cable connection recommended.
HELP	ARTERIAL PRESSURE		AP Trigger mode: Uses AP waveform to trigger. Recommended when ECG is not available or too noisy. NOT RECOMMENDED FOR IRREGULAR RHYTHMS.

KEY 1	KEY 2	KEY 3	HELP MESSAGE AND TEXT
HELP	INTERNAL		INTERNAL Trigger mode: Uses IABP internal signal for triggering. Used when no ECG or AP signal is available. ASYNCHRONOUS TO PATIENT CARDIAC ACTIVITY. Press INT again to confirm.
HOME	HELP	AP SCALING	Press AP SCALING to show current display scales for AP waveform. Current selection is highlighted. To change, press key under desired setting. Press HOME to exit or wait and screen will clear.
HOME	HELP	RECORDER SETUP	Press RECORDER SETUP to show choices. Select one or two waveforms, change speed and set timed recording. Choices are highlighted. To change, press key under selection. Waveforms cannot be changed while recording.
HOME	HELP	WEANING SETUP	AUTOMATIC WEANING not available at this time.
HOME	HELP	SHOW STATS	Shows ACAT operational status including DATE, POWER, ALARMS, RECORDER, HELIUM tank level and ASSIST RATIO. Press HIDE STATUS to clear display.
HOME	HELP	HEMO-DYNAMICS	Calculates two pressure differences from patient blood pressure: (PDP - PSP) and (PDP - BAEDP). Calculations based on last assisted beat.

KEY 1	KEY 2	KEY 3	HELP MESSAGE AND TEXT
HOME	HELP	AUDIO SETUP	Audio setup adjusts key or alarm volume. You may select alarm and key volumes separately. Use SOFTER/LOUDER keys to adjust selected function. Select ALARM VOLUME and AUDIO TEST to hear alarm tone. Key clicks may be turned on or off.
HOME	HELP	CLOCK SETUP	Changes clock date and time for pump and recorder. Press key under desired parameter. Press INCREASE/DECREASE to change. Press HOME to exit.

Home

Pressing the HOME key will return the display and multi-function keys to their original operating state.

Display Control

The DISPLAY FREEZE control key allows you to freeze approximately seven seconds of waveforms on the LCD. This feature is used for examining waveforms for adequate triggering, timing, and balloon pressure. Hemodynamic data continues to be updated.

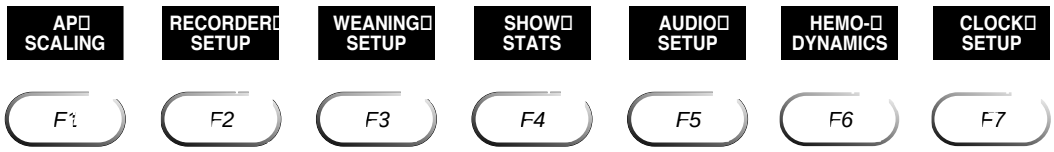
Display Control Key

Selection	Description
FREEZE	Freezes the waveform display; the moving waveform display returns when the FREEZE key is pressed a second time.

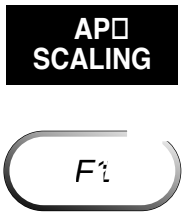
Multi-Function Keys

Below the LCD are located seven (7) multi-function keys. The operation which each performs is indicated directly above the key on the LCD. The active selection(s) are highlighted by reverse video. The multi-function keys may be accessed by pressing HOME or any multi-function key when no display is present.

In the normal operation mode the following functions will be displayed:

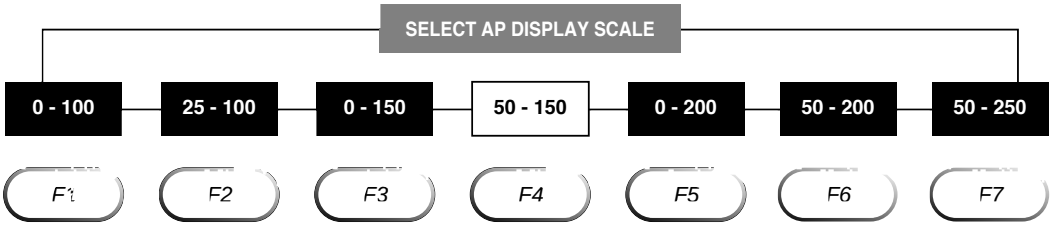


AP Scaling



Selects AP Scale for display and recorder. Selections are:

0-100
25-100
0-150
[50-150]
0-200
50-200
50-250



Default setting is 50-150.

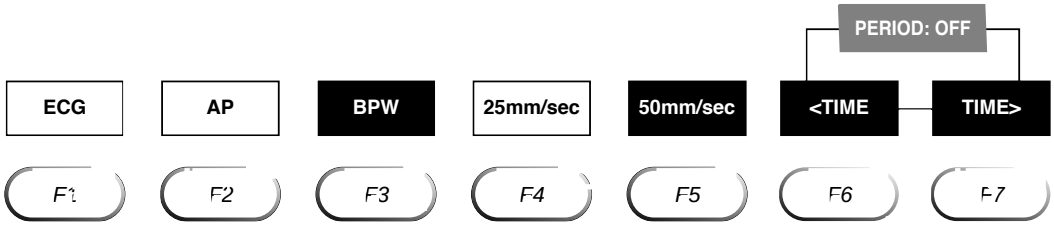
NOTE: This may also be accessed via the AP SELECT key. AP Scale selections are the same.

Recorder Setup

Selects waveforms to be recorded. Sweep speed and time interval for automatic recordings.

Presets:

WAVEFORMS	[ECG]	[AP]	BPW			
SPEED	[25]	50				
TIMED INTERVAL	[OFF]	2	15	30	60	120	240
QA LOG RECORDING	ON	[OFF]				

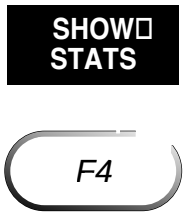


Recorder Scaling - AP Waveform		
Selection		**Description**
AP	0-100	(25.0mmHg /div dual trace, 12.5mmHg /div single trace)
DISPLAY	25-100	(18.75mmHg /div dual trace, 9.375mmHg /div single trace)
SCALE	0-150	(37.5mmHg /div dual trace, 18.75mmHg /div single trace)
	[50-150]	(25.0mmHg /div dual trace, 12.5mmHg /div single trace)
	50-200	(37.5mmHg /div dual trace, 18.75mmHg /div single trace)
	0-200	(50.0mmHg /div dual trace, 25.0mmHg /div single trace)
	50-250	(50.0mmHg /div dual trace, 25.0mmHg /div single trace)

Weaning Setup

Programmed Weaning is not available at this time. When it becomes available, the multifunction keys will appear as such:

Show/Hide Stats



This key will display a summary of all current pump operational settings as well as selected information which is tracked by the A*CAT*®1. SHOW STATS when pressed will display parameters below in the HELP message area. The multi-function key label will then change to HIDE STATS. This display will stay on screen for 30 seconds or until HIDE STATS is pressed or until HOME is pressed.

Stats displayed:

DAY–TIME	__/__/__:__:__ Displays current setting of date and time.
POWER STATUS	__ __ Volts Displays battery voltage and if the A*CAT*®1 is charging the battery, running on battery power, or checking power source.
ALARMS	____ ____ Displays the most recent alarm code and subcode (if any) that was issued.
WEANING	Not implemented at this time.
RECORDER	____ ____ mm/sec. Shows current recorder settings for Trace 1 and Trace 2 as well as sweep speed.
ASSIST RATIO	1:1
HELIUM TANK	__ psi

Audio Setup

The Audio Setup will allow the user to set the key volume and turn it on/off and independently set alarm volume. Select desired parameter to modify volume, then use < SOFTER LOUDER > keys to adjust volume to the desired level.

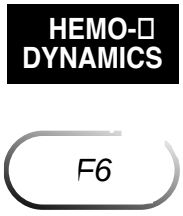
Options available for Audio Setup

<SOFTER/LOUDER>	Changes volume of alarms/key clicks in desired direction.
ALARMS VOLUME	Selects alarm volume for adjustment.
KEY CLICK VOLUME	Selects key click volume independently of alarms for adjustment.
KEY CLICK ON/OFF	Turns key click sound on/off.
AUDIO TEST ON/OFF	Initiates audio test to check speaker and audio controls for alarm tone.

Presets

Alarm Volume	ON	80%
Key Click	ON	20%
Audiotest	OFF	

Hemodynamic Calculations (Hemo Calcs)



This is a function which will automatically calculate the following pressure differences from the AP Waveform on the last assisted beat.

1 PDP-PSP
2 PDP-EDP

To obtain these calculations press the Hemo Calc key. The calculations will be displayed in the HELP area and recorded by date/time in the QA log under hemodynamics.

Clock Setup

Clock Setup allows the user to set the time and date for the pump. It is important that the clock be correctly set for accurate recording time as well as accurate date/time stamps in the QA log.

To set time, press the multi-function key under the desired parameter. The parameter will be highlighted. Move the time backward (F6) or forward (F7) as desired. Continue this same process for other parameters that require changes.

Balloon Inflation and Deflation Control

Precise control of inflation and deflation is governed by the assist ratio, inflation volume, triggering and timing operating functions. Maximum hemodynamic benefit is realized when all four of these mechanisms are set properly. The following paragraphs describe each mechanism and how their functions contribute to patient benefit.

Assist Ratio

Assist ratio settings are used to control balloon inflation and deflation frequency. You can choose to provide IABP assist with every cardiac cycle, every second, every fourth, or every eighth cardiac cycle. At start-up, the preset assist ratio is set at 1:2. By comparing assisted with unassisted pressures on the AP waveform, you can determine how the inflation and deflation points should be adjusted to optimize timing. After optimum timing has been achieved, the assist ratio is generally set at 1:1 to provide maximum IABP support to the patient.

You will usually maintain the assist ratio at 1:1 until the patient no longer requires constant IABP support. To avoid potential complications from sudden IABP withdrawal, you can use the assist ratio to wean the patient from IABP support gradually: first change the assist ratio to 1:2, then 1:4, then 1:8 until IABP can be terminated entirely. During operation, the A*CAT*®1 uses both assisted and unassisted beats to calculate PSP, PDP, EDP and MAP from AP signals, regardless of assist ratio.

Balloon Volume

Arrow International, Inc. balloon connectors are electronically coded to automatically deliver a preset volume. Precise control of the stepper motor allows you to manually adjust the volume in 0.5 cc increments. The complete inflation volume range is 0-50 cc, but you cannot set inflation volume greater than the balloon's maximum capacity when using an Arrow International balloon connector. A properly coded balloon connector should be used with all balloons, including those not manufactured by Arrow International. Pumping the balloon at a volume greater than its capacity can have serious clinical consequences. The balloon volume that the operator has selected to be pumped is displayed on the LCD.

When PUMP STNDBY is pressed, the A*CAT*®1 purges the pneumatic system of ambient air for four cycles, then fills it with helium. If PUMP ON is pressed without pushing PUMP STNDBY, pumping starts immediately after one purge cycle. When the pump is on, a pressure transducer in the internal helium line monitors the action of the stepper motor and bellows. This transducer is the source of the balloon pressure waveform displayed on the A*CAT*®1 display. If a small helium leak exists, the A*CAT*®1 will automatically refill the IAB line without interrupting pumping. If larger leaks are detected, the A*CAT*®1 alarm system will shut down the pump.

The A*CAT*®1 also has a thermo-electric baffle system (cold trap) to condense and remove moisture from the pneumatic lines. This is to prevent moisture from collecting in the tubing, where it will impede the flow of helium. Moisture is chilled and condensed into liquid. The liquid drains into a condensate collection bottle in the helium storage compartment behind the helium tank.

Triggering

The trigger mode is the logic criteria that the A*CAT*®1 uses to detect trigger points electronically. When the A*CAT*®1 recognizes a specific event in the cardiac cycle defined by the trigger mode, logical processes occur that culminate in balloon inflation and deflation. By continuously analyzing the patient's R-wave or AP waveform, the A*CAT*®1 is able to detect trigger points so that inflation and deflation occur consistently at the same points in each cardiac cycle. The A*CAT*®1 measures and predicts heart rate and can recognize sudden rate changes. It adjusts automatically for most variations in heart rate and arrhythmias. The A*CAT*®1 also has built-in safety mechanisms. For example, if an R-wave occurs that is inconsistent with the preceding beats (e.g., an ectopic beat), the A*CAT*®1 will automatically deflate the balloon and attempt to resume pumping based on the previous R-R interval.

The A*CAT*®1 relies on the ECG and/or AP signals to track cardiac events. Therefore, it is very important to obtain high-quality, reliable signals and to identify reliable trigger modes. The A*CAT*®1 is equipped with seven trigger modes (described earlier) in order to give you the flexibility you need to accommodate acute clinical situations. PATTERN, PEAK, A FIB, V PACE and A PACE are ECG trigger modes: the A*CAT*®1 analyzes the patient's R-R interval to detect trigger points. The ART PRESS trigger mode is based on the patient's AP waveform, while INTERNAL allows you to manually select a constant trigger rate if the patient has no myocardial activity.

A trigger mode may become unreliable as a result of changes in the patient's condition or clinical environment (e.g., the presence of electrosurgical units). In any acute clinical situation, you must be prepared to change trigger modes. It may also be useful to adjust the placement of ECG leads to improve the ECG signal. Although it is generally best to use an ECG trigger mode whenever possible, not all patients will have adequate ECG rhythms for triggering. Patients with ventricular fibrillation, extreme bradycardia (less than 40 BPM), agonal rhythms or Stone Heart Syndrome may require other forms of intervention and/or the use of other trigger modes. The most common use of each of the seven trigger modes was described in Section 3.3.

In addition, electrocautery and electrosurgical units can cause interference with the ECG signal. The degree of interference depends on the type of ESU in use and the power settings used to cut and coagulate tissue. A continuously operating ESIS circuit acts as a filtering mechanism to minimize this interference. ESIS may not eliminate interference completely. However, if persistent interference prevents you from finding a consistent ECG trigger mode, you may need to use the ART PRESS trigger mode.

If the patient has no myocardial activity at all (e.g., during bypass surgery), inflation and deflation can be set manually using the INTERNAL trigger mode. You can select any constant rate from 40 BPM to 120 BPM in 5 beat increments, using the multi-function keys when INTERNAL is selected.

Timing

After a reliable trigger mode has been selected, the A*CAT*®1 is able to trigger inflation and deflation to occur at precisely the same points in every cardiac cycle. The timing of these inflation and deflation cycles (i.e., at what points in the cardiac cycle they will occur) must be determined and monitored by the clinician. Conventional "Proper timing" requires balloon inflation to occur immediately after Aortic Valve Closure (AVC) at the onset of diastole, and deflation to occur immediately before Aortic Valve Opening (AVO) at the onset of systole. As explained in Section 1.1, this helps to balance the patient's myocardial oxygen supply and demand. If inflation and deflation are not timed properly, the benefit to the patient is reduced.

When you initiate counterpulsation by pressing the PUMP ON control key, inflation and deflation will occur at the preset points. You are then able to use the inflation and deflation control keys to optimize timing. You can assess the effects of these adjustments by observing key landmarks in the AP waveform: this procedure is described in detail in Section 5.1. If the patient's cardiac rhythm is regular, you will usually be able to achieve proper timing. However, if the patient's cardiac rhythm is not regular, the key landmarks on the patient's AP waveform will vary with each beat. You can adjust the inflation and deflation points to optimize timing. Even with a regular heart beat, you may need to adjust timing to accommodate changes in the performance of the patient's left ventricle. The cursor may be used to mark the desired point of inflation or deflation.

The blue horizontal scale at the bottom of the display shows the interval between trigger points (0% to 120% of the R-R interval for ECG trigger modes and the AP waveform for the AP trigger mode), and the green bar (red bar in AP trigger) indicates the inflation and deflation set points. The A*CAT*®1 allows you to adjust the inflation and deflation points within certain limits, defined as a percentage of the interval between trigger points. These ranges are summarized in the following table. The ranges for the ART PRESS mode differ from those for ECG trigger modes because of time differences between electrical and mechanical cardiac events. The numerical values represent the actual inflate/deflate settings as a percentage of the R-R or AP to AP waveform. The green or red bar represents the total inflation time within one cardiac cycle. A change in the color of the bar to yellow indicates that deflation timing is set >100% of the R to R interval. Check timing.

Trigger Mode(s)	Inflation Range	Deflation Range
PATTERN, PEAK,VPACE and APACE[3]	20% - 80%	30% -120%
A FIB	80 - 430ms after trigger	NA (set by the ACAT®1)
ART PRESS	0% - 35%	35% - 75%
INTERNAL	20% - 80%	30% -120%

A safety mechanism exists to prevent overlap of inflate/deflate settings.

EXAMPLE 1: Inflation timing (I) is set at 50% of the R-R interval and deflation timing (D) is set at 80%.

0% 120%

_____50% _____80% _____

(I) (D)

EXAMPLE 2: If the patient's heart rate were to increase, necessitating a change in inflation timing, the operator would depress the right arrow on the inflate control key.

0% 120%

_____75% ____80% _____

(I) (D)

[3] In the APACER mode, the R-R interval displayed is delayed by 100ms from trigger point because of the relationship between the atrial pacing spike and the cardiac cycle.

EXAMPLE 3: Continued changes to the inflate setting will affect a corresponding change in the deflate setting to maintain a 5% difference between inflation and deflation.

0% 120%

_____77% ____82% _____

(I) (D)

If the inflation and deflation timing becomes incorrect or sub-optimal for the patient, you must move the inflate marker to the left before attempting to correct deflation timing. This procedure is required whenever inflation timing approximates deflation timing.

WARNING

The operator must closely observe the effects of inflation timing on deflation timing whenever the settings are altered. Failure to do so may adversely impact the expected benefits of counterpulsation and have serious clinical sequelae.

According to conventional IABP theory, deflation should be set between 50% and 100% of the R-R interval. As you can see, deflation can be set beyond the R-R interval in some trigger modes. This is because the electromechanical delay is prolonged in some patients (e.g., those who are hypothermic or have hyperkalemic cardioplegia in the cardiac tissue). In these patients, deflation at 100% of the R-R interval may be too early (i.e., before AVO) to optimally reduce afterload. Thus, it may be necessary to deflate the balloon beyond 100% of the R-R interval. When you do this, an alarm tone will sound and a visual message will appear indicating that deflation has been set beyond 100% of the R-R interval. The timing bar will also become yellow when set beyond 100%. You should monitor the AP waveform continuously whenever deflation is set beyond 100%. Also record and monitor the numerical values for the exact timing setting.

WARNING

The operator must continuously monitor the patient's Arterial Pressure waveform whenever the deflation point is set beyond 100%.

Performance and Technical Specifications

The A*CAT*®1 is a technologically advanced, microprocessor based system designed to the highest standards for performance, reliability, versatility and safety. With its computerized control system, the A*CAT*®1 is highly automated, freeing the clinician to provide vital care to the patient.

Chapter 3 described the operating functions of the A*CAT*®1. This chapter details the A*CAT*®1 performance and technical specifications for your reference.

The contents of this chapter include:

4.1: ACAT®1 *Specifications* **4-3**

4.2: ACAT®1 *Classification and Symbols* **4-10**

A*CAT*®1 Classification 4-10
A*CAT*®1 Symbols and Definitions 4-11
A*CAT*®1 Outside Labeling Information 4-14

ACAT®1 Specifications

The ACAT®1 IABP System (Figure 4.1) design allows for rapid initiation of counterpulsation and is compatible with the output of most bedside monitors and direct inputs. It maintains precise IAB inflation and deflation timing based on the patient's current physiological condition, and automatically adjusts timing to accommodate variations in heart rate. The system's comprehensive diagnostic alarm system alerts the console of catheter malfunctions.

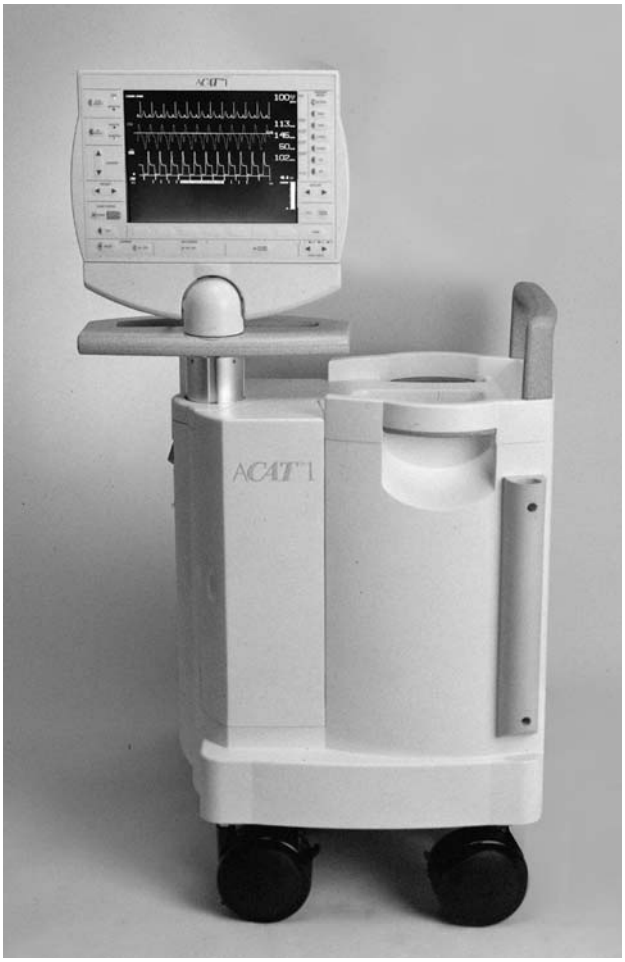


Figure 4.1: The ACAT®1 IABP System

The ACAT®1 technical specifications are summarized in the table on the following pages. Further discussion of the ACAT®1 performance and functions may be found in Chapter 3, Principles of Operation.

ACAT®1 Technical Specifications	
Dimensions	Monitor/Control Module: 9.25" high x 13.75" wide x 2.0" deep (23.5cm x 35.0cm x 5.0cm) Pneumatic Drive Module: 28.0" high x 12.0" wide x 20.0" deep (71.0cm x 30.5cm x 51.0cm)
Weight	Monitor/Control Module: 6 lb. (2.7 kg.) Pneumatic Drive Module: 80 lb. (36.3kg.)
Power Requirements	90-264 VAC 47-63Hz Average power consumption: 225 watts Maximum power consumption: 420 watts (surge)
Fuses	5 amp slo-blo
Battery Run Time	120 minutes (approximate, with full charge, 40 cc, 80 BPM, Assist Ratio 1:1) Optional 240 minutes with additional battery
Assist Ratios	1:1, 1:2, 1:4, 1:8
Environmental Specification	Operating Temperature: 0°C to 45°C Storage and Transport Temperature: -15°C to 40°C Storage and Transport Atmospheric Pressure: 200 hPa - 1060 hPa (150mm Hg - 796mm Hg) Storage and Transport Humidity: 15% - 80%
Pumping Rate	40-200 BPM
Lead Selection	ECG patient cable input: lead I, II or III with 3 lead cable or I, II, III, AVR, AVL, AVF, and V with 5 lead cable. From remote monitor: Phono-to-Phono or Phono-to-Nicolay

ACAT®1 Technical Specifications	
Triggering Modes	ECG PATTERN, PEAK and A FIB modes: microprocessor-based waveform comparison algorithms ECG A PACE and V PACE modes: – pacer recognition system triggers from pacer spikes – pulse widths from 0.1 to 0.5ms and pulse amplitude of ±5 mV or greater – pulse widths greater than or equal to 0.5ms and pulse amplitude of ±2 mV or greater Atrio-ventricular pacing: – maximum A-V interval of 250ms ART PRESS mode: – microprocessor-based waveform recognition algorithm INTERNAL mode: – constant-rate trigger, adjustable from 40-120 bpm
Triggering Ranges	All modes except ART PRESS and A FIB: – inflation 20-80% of R-R interval – deflation 30-120% of R-R interval ART PRESS mode: – inflation 0-35% of R-R interval – deflation 35-75% of R-R interval A FIB mode: – inflation 80-430ms after previous R-wave deflation – deflation on the R-wave

ACAT®1 Technical Specifications	
Color Display	Multi-color, three-channel, high-resolution, LCD (Liquid Crystal Display),(480x640) 10.4 inch diagonal ECG Waveform: green; contrasting white color on assisted portions Arterial Pressure Waveform: red; calibrated in mmHg for direct reading, contrasting white color on assisted portion of unassisted beats Balloon Pressure Waveform: – blue; calibrated in mmHg for direct reading – sensed through internal strain-gauge transducer Timing Reference Display: – Highlight displays inflate and deflate positions relative to the R-R interval (except A FIB) on unassisted beats – Color matches trigger mode and changes to yellow for deflation >100% Waveform freeze interval: 7 seconds Physiological Data: – Heart Rate (HR) – Peak Systolic Pressure (PSP) – Peak Diastolic Pressure (PDP) – End-Diastolic Pressure (EDP) – Mean Arterial Pressure (MAP) – Balloon Volume (B. VOL) – Optional: BPW plateau pressure Heart Rate: – derived from ECG or Arterial Pressure triggering signals – value averaged over four beats and updated every beat Arterial Pressure Data: – Peak Systolic Pressure (PSP) – Peak Diastolic Pressure (PDP) – Aortic End–Diastolic Pressure (AEDP) – each beat sampled and pressure automatically updated every beat – Peak Diastolic Pressure updated at each assisted beat (zero value given when no assist seen)

ACAT®1 Technical Specifications

Color Display (cont.)	Displayed Parameter Accuracy: – Heart Rate (other than internal trigger mode) +/- 2% at regular heart rhythm – Heart rate (internal trigger) +/- 1%, +/- 1 digit at all settings – PSP & EDP +/- 1%, +/- 1 digit from 40 bpm to 120 bpm and correct inflation/deflation timing – PDP +/- 1%, +/- 1 digit assisted beats from 40 bpm to 120 bpm and correct inflation/deflation timing; 0% unassisted beats – MAP +/- 1%, +/- 1 digit – Battery Voltage +/- 2% – Balloon volume +/- 10% – Helium supply pressure +/- 15% – Real time clock +/- 1 minute (display resolution in minutes) – Optional: BPW plateau pressure +/- 2% Operating Information: – helium tank pressure (auto scaling) – alarm/battery charging status – IAB volume (delivered) – assist ratio – trigger mode Trigger Signal: flashing heart symbol and white overlay on ECG Cursor: – horizontal cursor AP/BPW waveforms – numerical value provided Diagnostics: alphanumeric messages indicate that potential problems exist
Strip Chart Recorder	Dual-Channel Thermal Array Recorder: – dot matrix with integral event marker – records up to two of the following: ECG, Arterial Pressure, Balloon Pressure waveforms – assist interval indicated on top margin of strip when purging and when pumping – 40mm grid with 5mm divisions printed – user programmable demand strips at 2,15, 30, 60 minutes and 2 and 4 hour intervals – assist ratio – IAB volume delivered/ECG lead/Timing Settings/Trigger Modes – Automatic recordings of Class 1 Alarms – Optional: BPW plateau pressure

ACAT®1 Technical Specifications	
	Speeds: 25 or 50mm/sec. (±5% of rated speed) Paper: 50mm (±0.03mm)-wide, blank thermal paper (Roll Diameter not to exceed 5.4cm) Resolution: 400 dots/inch @ 25mm/sec.
Operating Gas	USP helium **WARNING: Do not use oxygen or any drive gas other than USP helium.**
Helium Tank	Disposable 500psi canister or 2000psi disposable/refillable cylinder
Volume/Pressure Control	Closed loop system
Water Vapor Removal	Solenoid-actuated, thermo-electric baffle system removes moisture from pneumatic lines. Collection bottle can be emptied without interrupting operation.
Gas Drive	Stepper motor-driven bellows (helium gas drive only)
Pumping Volume	0-50 cc in 0.5 cc increments
ECG Low Level Filtering	Diathermy and 50/60Hz notch 25Hz Low pass ESIS ON
Applicable Standards	Designed to IEC 601-1 and UL 544
Polarity	Automatic processing of positive or negative triggering signals (Arterial Pressure must be positive)
ECG Low Level Bandwidth	0.5-25Hz
Leakage Current	Less than 10 µA
Line Isolation	120 db at 60Hz to ground
Defibrillator Protection	Input protected up to 400 joule, 5 kV peak defibrillator discharges at 20-sec intervals
Pacer Rejection	Input amplifier rejects pacer spikes: – at 0.1 - 0.5ms pulse widths, pulse amplitude of ±5 mV or greater rejected – at 0.5ms pulse widths, pulse amplitude of ±2 mV or greater rejected

ACAT®1 Technical Specifications

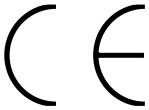
Inputs and Outputs	ECG MON input (high-level input): ± 6V full scale accepts ECG signals from remote monitor ART PRESS input: calibrated at 100mmHg/V accepts AP signal from remote monitor ECG MON output (high-level output): ±6V full scale provides ECG signal for display on remote monitor ART PRESS output: 100mmHg/V BALLOON PRESS output: 100mmHg/V ASSIST INTERVAL: TTL (used for interactive simulator connection) ECG (patient cable input): – for input of 3- or 5-lead patient cable or Phono-to-Nicolay cable – maximum input 10 mV differential ARTERIAL PRESSURE (transducer cable input): compatible with any pressure transducer with output equivalent to Spectramed transducer (50 µV/V/cm Hg) BALLOON CONNECTOR: electronic pins sense resistor value of IAB connector for input of IAB size DATA COMMUNICATIONS CHANNEL I: DB-9 Connector (RS232) for serial transmission of hemodynamic values, current alarms, time and date. MODEM: for connection to a PC via phone line for remote system monitoring FLASH CARD PCMCIA standard for storing data or downloading custom setups

A*CAT*®1 Classification

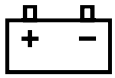
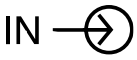
Unit is classified as Class I Type CF device under IEC 601-1 Standard. Unit is classified for degree of protection against ingress of liquids as drip proof (IPX1).

A*CAT*®1 Symbols and Definitions

The following pages show the symbols, and definitions of the symbols, used on the A*CAT*®1 IABP.

Symbol	Description
	Recycle lead
	Plus, positive polarity
	Minus, negative polarity
JUNC +	Plus, positive polarity
JUNC-	Minus, negative polarity
	Compliance to EMC directive 89/336/EEC
AP	Arterial pressure signal
ECG	ECG signal

Symbol	Description
	Balloon pressure signal
	Alternating current
	Direct current
	Equipotentiality
	Attention, consult accompanying documents/refer to the manual
	"Off" (only for a part of the equipment)
	"On" (only for a part of the equipment)
	Defibrillator-proof type CF equipment
	Replace fuse as marked

Symbol	Description
	Battery
	Input signal
	Output signal
	Assist interval signal for patient simulator
	Electrostatic sensitive devices
	Alarms off
DATA OUT	Hemodynamic data output signal
SN	Serial number

A*CAT*®1 Outside Labeling Information

I/O Panel:

DANGER: RISK OF EXPLOSION IF IN USE IN THE PRESENCE OF FLAMMABLE ANESTHETICS label is located on the lower left corner of the I/O Panel.

CAUTION: GROUNDING RELIABILITY CAN ONLY BE ACHIEVED WHEN EQUIPMENT IS CONNECTED TO AN EQUIVALENT RECEPTACLE MARKED 'HOSPITAL GRADE' label is located on the lower right corner of the I/O Panel.

SERIAL NUMBER label which includes unit serial number and power rating is located on the lower right corner of the I/O Panel.

WARNING: RISK OF FIRE, REPLACE FUSE AS MARKED label is located on the lower left corner of the I/O Panel. Please refer to the Operator manual for replacement fuses information.

Helium Compartment:

CAUTION: HELIUM USE ONLY label is located in the helium compartment.

FIELD CHANGE LEVEL label which includes unit Serial Number and unit field change level number is located in the helium compartment.

DC CIRCUIT BREAKER for internal batteries is located in the helium compartment.

Left and right side panels:

CAUTION: TO REDUCE THE RISK OF ELECTRIC SHOCK, DO NOT REMOVE COVER, REFER SERVICE TO QUALIFIED SERVICE PERSONNEL label is located on the lower section of the left and right side panels.

Battery:

SEALED LEAD BATTERY MUST BE RECYCLED OR DISPOSED OF PROPERLY label contains information on the lead contents and battery ordering part number information; label is located on the battery surface.

Operating Procedures

This chapter provides step-by-step instructions for operating the A*CAT*®1 IABP System under a variety of circumstances. Although these instructions are designed to walk you through the initiation, maintenance and withdrawal of balloon pumping, it is assumed that you have read and thoroughly understand all of the chapters in this manual, especially Chapter 3, Principles of Operation, which explains how the A*CAT*®1 works, and outlines the location of all function control keys.

If you have questions or difficulties during the operation of the A*CAT*®1 IABP System, refer to Chapter 9, Troubleshooting, which provides troubleshooting guidelines and refers you to the 24 hour telephone number for Arrow International service.

The contents of this chapter include:

5.1: *Operating Instructions* **5-3**

Summary 5-3
Preparation 5-5
Patient Connections 5-6
Choosing a Trigger Mode 5-10
Initiating Counterpulsation 5-12
Optimizing Inflation/Deflation Timing 5-13
Assessing the Balloon Pressure Waveform 5-17
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Weaning the Patient 5-21

5.2: *Clinical Environments* **5-23**

The A*CAT*®1 Transport 5-23
The A*CAT*®1 in the Operating Room or
Catheterization Lab 5-26
The A*CAT*®1 in the Intensive Care Unit 5-28
The A*CAT*®1 in Emergency Conditions 5-28

Summary

The steps to initiate and maintain counterpulsation are briefly summarized below. The remainder of the chapter explains these steps in detail.

WARNING

The A*CAT*®1 IABP System requires a trained operator who has read and understands all sections of this manual prior to using the A*CAT*®1 IABP System. Only medical personnel trained in the use of IABP devices and acting under a physician's orders should operate this system.

A. A*CAT*®1 *Preset (Default) Startup*

1. Plug in the power cord and turn on the console by pressing the power switch located on the patient interface panel of the console. If AC power is applied to the A*CAT*®1, the POWER INDICATOR LED on the front panel will illuminate.
2. When the A*CAT*®1 is turned on, all of the system's preset operating functions are automatically selected. The preset selections are:
   - Recorder: OFF (ECG/AP/25mm sec.)
   - Trigger Mode: PATTERN
   - Pump Status: OFF
   - ECG Lead: II/for direct ECG or Phono-Nicolay Low Level (if signal is available from bedside monitor)
   - Assist Ratio: 1:2
   - Calibration: AUTO
   - Display Range (AP): 50 - 150mmHg
   - Alarms: ON
   - Balloon Volume: Full Volume (based on IAB connector)

   Note: ESIS (Electrosurgical Interference Suppression) is operating at all times.

   Note: ECG Autogain operates continuously.

   These preset selections are clinically appropriate for most patients and allow you to start pumping rapidly, simply and safely. Depending on clinical conditions, you may choose to adjust these preset selections before or after initiating counterpulsation. The preset selections are those most commonly used by operators at system start-up.

3. Ensure that you have sufficient power, helium, recorder paper and other supplies.
4. Connect an ECG source to the A*CAT*®1 using one of the following:
   - a 3- or 5-lead ECG patient cable to the green ECG input connector.
   - a high-level monitor using a Phono-Nicolay to the green input connector
5. Select the ECG lead that provides the clearest, largest QRS complex.
6. Connect an AP source to the A*CAT*®1 using one of the following:
   - a low level signal using a compatible pressure transducer connected to the orange ART PRESS input connector. AP Select: Transducer
   - a high-level monitor using a Phono-to-Phono connector to the phono jack ART PRES input connector. AP Select: Monitor
   - Zero the transducer.
7. Evaluate each potentially appropriate trigger mode. Select the most reliable trigger mode.

   If persistent interference prevents you from finding a consistent EGG trigger mode, you may need to use the ART PRESS trigger mode.
8. Connect the balloon plug securely to the balloon connector.
9. Verify the balloon volume by observing the BALLOON VOLUME displayed on LCD. Adjust inflation volume, if appropriate.
10. Press PUMP STNDBY, then press PUMP ON.
11. Check to make sure the assist ratio is set on 1:2.
12. Optimize timing by using the inflate/deflate control keys to adjust the inflation and deflation points.
13. Make sure the balloon pressure waveform is normal and shows no indications of helium leaks.
14. Set the assist ratio to 1:1.
15. To maintain balloon pumping, check the ECG leads, trigger source, timing, balloon inflation volume, balloon pressure waveform, hemodynamic data, helium supply and alarm status every hour. Respond to all alarms promptly.
16. See the guidelines at the end of this section to wean the patient from IABP support.

B. Optional startup with Flash Card

If you have programmed startup settings specific to your environment and have the Flash Card available, you may choose to initiate the A*CAT*®1 with those settings. To do so:

1. Place Flash Card in front panel recepticle *prior* to power on.
2. Press POWER ON.

Settings will now default to those programmed on Flash Card. Follow steps 3-16 of preset startup instructions to continue startup.

Preparation

The Operational Checkout procedure described in Section 8.1 is designed to verify the A*CAT*®1 operational readiness. The instructions in this chapter assume that the Operational Checkout has been performed recently (within a week). Follow the preparation instructions below while the physician is inserting the balloon.

WARNING

Do not use solvents (e.g., acetone or other degreasing agents) to prepare the skin. They may damage the IAB catheter or other plastic components of the system.

If rapid initiation of counterpulsation is required, see "The ACAT®1 in Emergency Conditions" in Section 5.2 to set up the ACAT®1 and begin pumping as quickly as possible.

1. Press the power switch located in the center of the patient interface panel. The power switch and the LCD should illuminate.

   *The A*CAT®1 *should already be plugged into a grounded AC power supply. If the system is not secured, engage the wheel brakes with your feet to secure the* A*CAT*®1.

   If Flash Card is to be used, place in recepticle prior to POWER ON.

2. If "SYSTEM RUNNING ON BATTERY" is displayed, the A*CAT*®1 is not receiving AC power. Call a qualified person to check the AC outlets for power. A fully charged battery will power the A*CAT*®1 for a minimum of 120 minutes.

   Note: Battery light "on" indicates battery at 80% or greater.

3. Double-check the helium and recorder paper supplies. These should have been replenished during the Operational Checkout.

   If there is 100psi or less of helium, see the instructions in Section 8.1 to replace the helium tank.

WARNING

Be prepared to maintain IABP operation in critical situations by having a backup IABP system and extra helium bottles ready in case of system failure or helium depletion.

Patient Connections

Follow the instructions below to connect ECG and AP input signals to the A*CAT*®1. Proper functioning of the A*CAT*®1 requires either an ECG or AP signal connection, however, it is **highly recommended** to have both.

ECG Connection

1. To optimize the ECG signal and minimize artifacts, check to make sure the electrodes have been placed properly:
   - Use pre-gelled, electrochemically reversible type electrodes (if using disposable electrodes). **CAUTION: Do not use electrodes after expiration date.**
   - **Make sure gel is not dried out.**
   - Shave excessive hair from electrode sites. Clean skin with alcohol pad or mild soap. Rub the skin slightly until it is reddened.
   - Place the three or five leads on bony prominences as illustrated in Figure 5.1. (RL and V lead on 5 lead cable only.)
   - Attach the color-coded lead wires to the electrodes and secure clips in place.

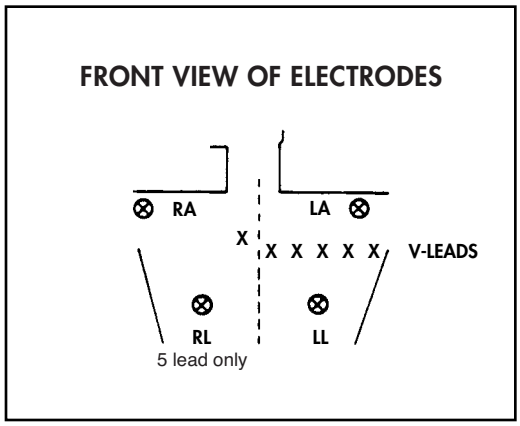


Figure 5.1: ECG Electrode Placement, 3- or 5-lead

Standard Lead Configurations

Lead	Active Electrodes		Reference
I	RA (white)	LA (black)	LL (red)
II	RA	LL	LA
III	LA	LL	RA
AVR	RA		RL (green)
AVL	LA		RL
AVF	LL		RL
V	V (brown)		RL

2. Make one or both of the following connections (Figure 5.2):
   - Low level: ECG patient cable (trunk and clip) from patient
   - Low level: Phono-Nicolay from High-level Monitor to green Nicolay connector
   - Optional backup: Phono-to-Phono cable from high-level monitor to ECG MON

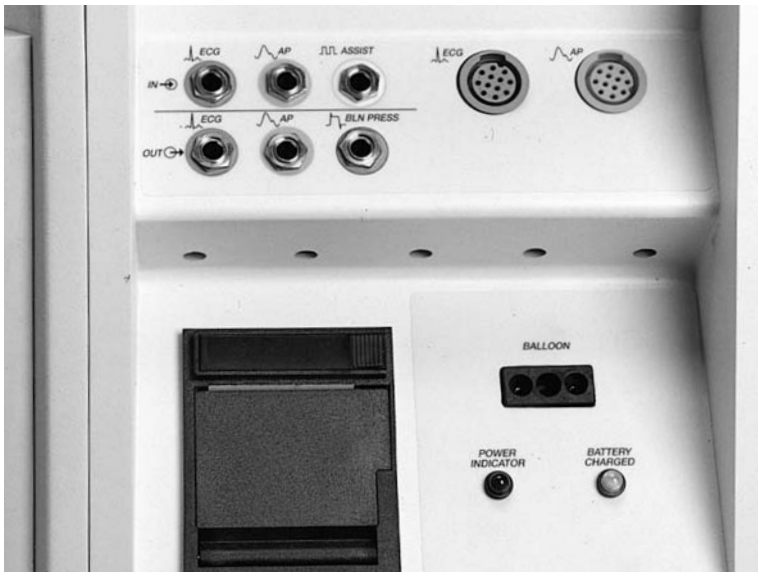


Figure 5.2: ECG Connectors

3. Confirm that ECG leads RA, LA and LL are correctly connected to the patient cable (RL and V leads for 5 lead cable).
4. If your input is a low-level signal, select ECG source by pressing the SELECT control key in the ECG SELECT section of the keypad. To select LEAD I, LEAD II, LEAD III, AVR, AVL, AVF or V, press ECG SOURCE SELECT. Lead II is the preset. The seven multi-function keys will now indicate all available leads based on the cable type (3 or 5 lead). At each lead selection, stop to evaluate the green ECG waveform displayed on the LCD for R-wave amplitude, definition of complexes and steady baseline. For a high-level signal using Phono-to-Nicolay cable, Lead II must be selected. For a high-level signal using Phono-to-Phono cable, select MONITOR and make sure the LED is lit.

   Lightly tap each electrode contact with your finger while observing the ECG trace on the LCD. If artifacts do not appear, a good contact has been made. If artifacts do appear, assure that the electrodes have good skin contact.
5. Select the ECG lead that consistently provides the clearest, largest QRS complex.

   To obtain a good triggering signal, it is very important to have a high quality ECG trace. White overlays on the ECG trace indicate the presence of a triggering signal. If you are not receiving a good ECG signal on any lead, consider manipulating the leads or removing and reattaching the leads in order to obtain a clear ECG signal.
6. ECG AUTO GAIN is continuous and should provide optimal QRS amplitude. However, MANUAL GAIN may be needed for some patients. See section 3.3 for more information.
7. Make sure that the red heart symbol icon flashes on the LCD with every heart beat, and the LED on the selected TRIGGER control key is also flashing consistently.

   If there is no flashing heart icon, the ACAT®1 *is not detecting a triggering signal (a recognizable EGG waveform). Check the electrode contacts and placement, and see "Choosing a Trigger Mode" in this section.*

8. Note that the white overlay on the ECG and AP trace shows the preset assist interval.

   The preset assist interval is calculated by the A*CAT*®1 *to be hemodynamically safe for the patient. You may refine this interval when you optimize timing later in this section. If the physician wishes to start out with different inflation and deflation points, use the inflate/deflate control keys located on the sides of the* A*CAT*®1 *keypad to adjust timing accordingly.*

   If a white overlay does not appear on the ECG trace (with each cycle, corresponding to the ratio of assist), the A*CAT*®1 *is not detecting a triggering signal. See "Choosing a Trigger Mode."*

Arterial Pressure Connection

1. Make one of the following connections:

   - Low level: pressure transducer to ARTERIAL PRESSURE transducer input
   - High level: Phono-to-Phono cable from the patient monitor to ART PRESS input

   If you are making the "high-level" connection, make sure the monitor's output is compatible with the A*CAT*®1: it should be calibrated to 100mmHg/volt. If you have made a low-level input connection, you can also connect a Phono-to-Phono cable from the ART PRESS output connection on the A*CAT*®1 to a high-level monitor.

2. If two arterial pressure sources are connected to the A*CAT*®1, you may select the AP source to be displayed and used by the pump via the AP SOURCE SELECT. To change AP SOURCE, press AP SELECT until LED next to desired selection is on. This selection will be the source of the AP waveform to the pump. Instructions for calibration of transducers are contained in Chapter 6 (you can also modify the AP waveform display range).

3. Observe the red AP waveform displayed on the LCD. The red grid on the right side of the LCD provides a calibrated display. The waveform should have a clearly discernable Dicrotic Notch (DN), and should look similar to that shown in Figure 5.3.

   If the waveform does not resemble that shown in Figure 5.3, check all pressure monitoring tubing and the catheter for air or possible clots. Optimum timing is most accurately achieved by observing the AP waveform. It is important to obtain a high-quality, resonance free, AP trace.

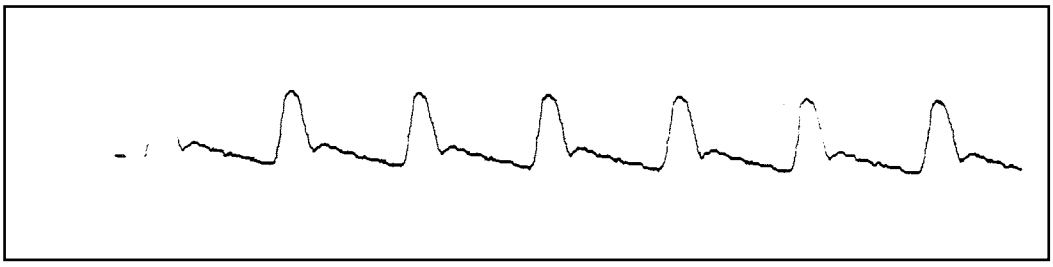


Figure 5.3 Typical Arterial Pressure Waveform

4. Zero by opening the transducer to air and pressing the AP SOURCE SELECT key. The seven multi-function keys will then change to the AP SCALING, ZERO and CALIBRATION OPTIONS.
5. Press ZERO. ZEROED will be displayed in the message area.
6. Select the display scale most appropriate to the patient's arterial pressure. Preset scale is 50-150mm/Hg.
7. Observe a white timing highlight on the arterial pressure waveform on all unassisted beats. This confirms a valid trigger and allows the clinician to fine tune timing prior to pump start. Adjust white bands to the beginning of the DN and to just prior to the following PSP upstroke. White highlights will disappear when PUMP ON is pressed, on all assisted beats.

   When you have made the ECG, Arterial Pressure connections, the ECG and AP waveforms and the patient's hemodynamic data will appear on the LCD. If they do not appear, repeat the previous steps for ECG and Arterial Pressure connections.

Choosing a Trigger Mode

Choosing a reliable, consistent trigger mode is critical to providing on-going IABP support to the patient. It is important to consider all of your triggering options: find more than one reliable trigger mode so that you can change to a new trigger mode easily if necessary.

1. Trigger Modes are selected by depressing the appropriate control key in the TRIGGER MODE section of the keypad.

WARNING

The INTERNAL trigger mode should be used **only if the patient has no myocardial activity and/or ventricular ejection.** You must press the INT control key in the TRIGGER MODE section of the keypad twice if you wish to operate the A*CAT*®1 IABP in the INTERNAL trigger mode. An audible alarm will sound to alert you that an ECG is present when INTERNAL is selected. A warning message "INTERNAL" is displayed continuously above the ECG trace when INT is selected.

WARNING

Arterial Pressure triggering is not recommended if the patient is in atrial fibrillation or has tachyarrhythmias. These conditions produce irregular Arterial Pressure waveforms.

WARNING

With acutely ill patients, both the ECG and Arterial Pressure waveforms may be inadequate for triggering.

WARNING

Certain monitors may process pacing signals and reinsert spikes that do not meet A*CAT*®1 criteria. In this case, the patient cable must be used to use pacer triggers.

Recommended IABP Triggers							
Rhythm	**Pattern** R-Wave Criteria: 25-135msec.	**Peak** Wide Complex QRS	**AFIB** Varying R-R Automatic R-Wave deflation	**V-Pace** 100% Paced	**A-Pace** 100% Paced	**AP** (Consistent BP)	**INT** Rate 80 automatic Range 40-120
NSR	*	*	*[4]			*	
S Brady	*	*	*[4]			*	
S Tachy	*	*[5]	*[4]			*	
Cautery Interference						*	
NSR with Premature Beats	* (atrial)[2]	* (vent)	*				
NSR with Pauses	*	*	* if severe			*	
PAT/SVT	*	*				*	
Atrial Flutter	*	*	* if irregular				
Atrial Fibrillation	*[3]	*	*				
Atrial Pacing	* demand	* demand			* 100% paced	*	
Ventricular Pacing		* demand		* 100% paced		*	
A-V Pacing		* demand		* 100% paced		*	
RBBB, LBBB		*				*	
Ventricular tachycardia		*				*	
CPR						* first choice	*
Bypass-Pulsatile flow testing							*

[1] Note: No capture beat needed for trigger. [2] Depends on type and number of premature beats. [3] For significant irregularity use Peak.
[4] If Real Time Timing is desired [5] May be preferred for HR > 140 bpm

Note: *Patients must be 100% paced to use the V PACE and A PACE trigger modes. Unless the patient is 100% paced, you will probably use the PATTERN or PEAK mode.*

2. For each trigger mode that is potentially appropriate for your patient, look for a consistent white overlay on the ECG and AP trace and a flashing heart icon on the LCD. The white overlay on the ECG should correspond with the assist ratio. The selected trigger mode control key LED will also flash if the A*CAT*®1 is detecting an adequate triggering signal.
3. Note the trigger modes that provide consistent triggering signals.
4. Select the best (most reliable) trigger mode. If PATTERN is reliable, this is usually the best trigger mode to begin pumping.

   An Automatic Response alarm will alert you if the A*CAT*®1 *loses the triggering signal. If this happens, change to another trigger mode. The system will provide you with corrective action steps. Further information is available in Chapter 9.*

   Note: If Real Time Deflation is desired as the method of timing, select the Afib Mode.

   Warning: Use of Afib trigger mode may produce late deflation which could compromise cardiac output. Carefully monitor hemodynamics when Afib Trigger is used or if deflation is set beyond 100%.

Initiating Counterpulsation

After you have selected a reliable trigger mode, follow the steps below to initiate counterpulsation.

1. Connect the balloon plug securely to the balloon connector on the front of the console. This sets the inflation volume to the maximum volume of the balloon.

> **WARNING**
> A properly coded balloon connector should be used with all balloons, including those not manufactured by Arrow International. Using a balloon connector coded for a volume greater than that of the balloon can have serious clinical consequences. Verify balloon volume prior to operating the pump, as described in section 5.1.

2. If you wish to reduce the inflation volume to lower than the balloon's capacity, depress the BALLOON VOLUME control key. The multi-function keys will change to allow you to change balloon volume.

   a. Increase or decrease as desired.

   b. You may return to full volume (determined by the balloon connector) by pressing the FULL VOLUME key.

> **WARNING**
> If an IAB is suspected of being occlusive, do not reduce the IAB volume to less than 2/3 of the balloon's capacity. To prevent thrombus formation, pump the balloon at its maximum capacity for five minutes every hour. A smaller IAB volume should be considered.

3. Press the STNDBY control key, located in the PUMP STATUS section of the keypad, to purge the balloon line of ambient air and refill the pneumatic system with helium.

   The system will complete four purge cycles, then stop. You must perform step 4 to initiate balloon inflation and deflation.

4. Initiate counterpulsation by pressing the ON control key. A moving balloon pressure waveform will appear on the LCD.

   To stop pumping temporarily, press STNDBY. Pressing ON will cause pumping to resume immediately. The balloon pressure waveform can be displayed on an external monitor by connecting a Phono-to-Phono cable to the BAL PRESS output connector on the A*CAT*®1 console.

Optimizing Inflation / Deflation Timing

Optimum timing provides maximum hemodynamic benefit to the patient. After you have selected a reliable trigger mode, carefully study the red AP waveform with white timing highlight on the LCD, then follow the instructions below to optimize timing for that trigger mode.

WARNING

Do not attempt to adjust timing based on ECG or Pacer waveforms. Inflation and deflation points should be set based on the Arterial Pressure waveform. Monitor this waveform to achieve optimum hemodynamic benefit.

1. Check to confirm that the assist ratio is set on 1:2. This will allow you to compare augmented with unaugmented beats.

   If 1:2 is not displayed, press the # left or right 3 arrow key in the ASSIST RATIO section of the keypad, until 1:2 is selected.

2. Adjust the inflation point:

   - Depress the "LATE" 3 arrow of the inflate control key until you can clearly see the DN on the AP waveform.
   - Depress the # "EARLY" arrow of the inflate control key until the white overlay is at the beginning of DN (40ms in front of DN) and the DN is no longer visible when pumping.

WARNING

Do not continue to move the inflate point to the left, even to increase PDP further. Early inflation can compromise systole.

WARNING

The operator must closely observe the effects of inflation timing on deflation timing whenever the settings are altered. Failure to do so may adversely impact the expected benefits of counterpulsation and have serious clinical sequelae.

WARNING

The operator must continuously monitor the patient's Arterial Pressure waveform whenever the deflation point is set beyond 100%.

   - Compare the AP waveform to Figure 5.4a. Note the V-shaped curve between the PSP and PDP peaks. PDP should be greater than PSP.

3. Adjust the deflation point:
   - Depress the # "EARLY" arrow of the deflate control key to see its effect on the AP waveform. Note the rise in APSP (early deflation).
   - Depress the "LATE" 3 arrow of the deflate control key to lower APSP and BAEDP. The white overlay should end just prior to the systolic upstroke. **If BAEDP starts to rise, depress the "EARLY" arrow of the deflate control key to deflate earlier.**
   - Compare the AP waveform to that in Figure 5.4a. APSP should be less than PSP, indicating the effectiveness of counterpulsation. BAEDP should be less than AEDP.

   If you have set the deflation point beyond 100% of the R-R interval, a Class 3 Alarm will appear on the display both numerically and by a change in the timing bar color to yellow.

4. Compare the AP waveform with those in Figures 5.4a-5.4e to ensure that you have achieved optimum timing.

   If your AP waveform does not resemble that in Figure 5.4a, repeat steps 1-3 to achieve optimum timing.

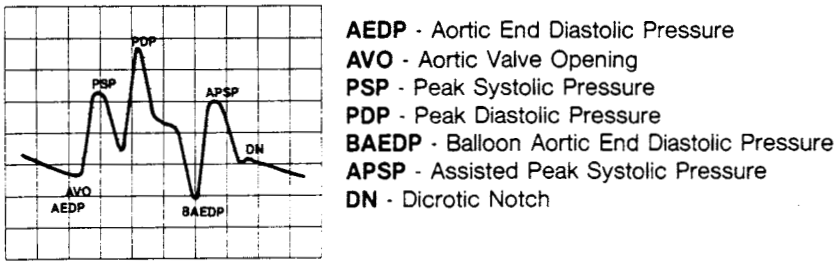


Figure 5.4a: Arterial Pressure Waveform (Optimum Timing)

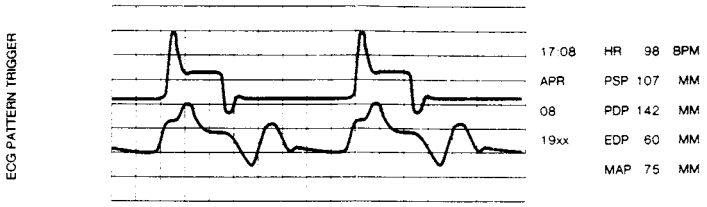
5. To automatically calculate Assisted to Unassisted Pressure differences, press multi-function key "HEMO CALCS. The following calculations will be performed:

1:1, 1:2, 1:4, 1:8	PDP-PSP
	PDP-EDP

6. Note the numerical values of the Inflate and Deflate settings.

Early inflation

If the balloon inflates before Aortic Valve Closure (AVC), the increase in aortic pressure will cause premature AVC, thus reducing Stroke Volume (SV). If inflation occurs very early, some blood may be regurgitated into the left ventricle. If the AP waveform shows early inflation, depress the "LATE" 3 arrow of the INFLATE CONTROL key to set a new inflation point closer to the DN.

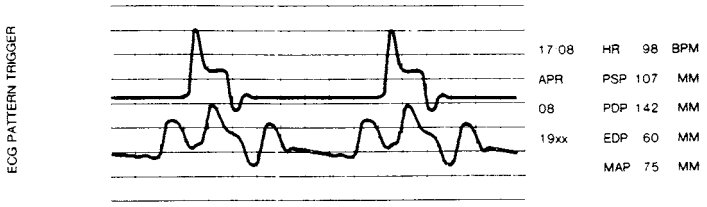


Result: Premature closure of the aortic valve reducing stroke volume.
Action: Assess the position of the DN on the assisted systole. Move inflation control to the right.

Figure 5.4b: Early Inflation

Late inflation

If inflation occurs after the DN, aortic pressure will decrease before inflation occurs. This results in a lower PDP and decreased coronary perfusion. Depress the # "EARLY" arrow of the inflate control key to inflate earlier.

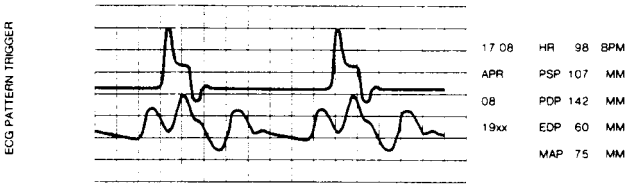


Result: Decreased perfusion pressure to the coronary arteries.
Action: Assess position of the DN on the assisted systole. Move inflation control to the left.

Figure 5.4c: Late Inflation

Early deflation

Deflation should occur just before ventricular ejection. If deflation occurs too early, blood will rush back to fill the aorta before ejection occurs. APSP will not be less than PSP: cardiac workload has not been reduced. On the waveform, assisted systole does not show the effect of afterload reduction, and BAEDP is shallow and returns to the baseline pressure. Depress the "LATE" 3 arrow of the deflate control key and observe the reduction in APSP.



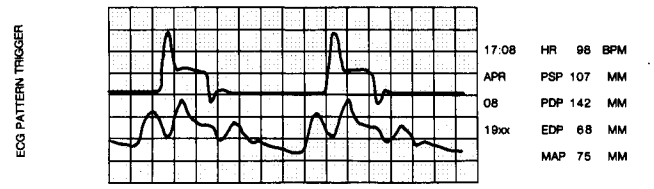
Result: Afterload is not significantly reduced. Balloon deflates during left ventricular filling, thus causing retrograde flow. Aortic pressure equilibrates and pressure is returned to normal AEDP, thus causing no change in afterload.

Action: Assess reduction of afterload on APSP and BAEDP. Move deflation control to the right. (later) R

Figure 5.4d: Early Deflation

Late deflation

The balloon is still inflated when the left ventricle ejects. Thus the pressure against which the ventricle ejects (afterload) is higher than it would be without IABP. Take corrective action by depressing the # "EARLY" arrow of the deflate control key. BAEDP should be less than the patient's AEDP.



Result: Increased workload of the left ventricle with impedance of stroke volume, thus prolonging Isovolumetric Contraction, increasing myocardial osygen consumption.

Action: Assess pressure difference between BAEDP and PAEDP. Move deflation control to the left. L (earlier)

Figure 5.4e: Late Deflation

5. After you have achieved optimum timing, press the left arrow key in the ASSIST RATIO section of the keypad, until 1:1 is selected. Now every heart beat will be assisted, and the white highlights on the AP waveform are no longer displayed.
6. If you lose a reliable trigger signal and change to a new trigger mode, repeat steps 1-5 to optimize timing for this mode. Since each trigger mode has specific timing settings memory, you will generally only need to reset timing when a trigger mode is first selected. However, timing should always be assessed when the trigger mode is changed. PATTERN and PEAK share a common memory for timing.

Assessing the Balloon Pressure Waveform

1. Compare the blue balloon pressure waveform on the LCD with Figures 5.5a-5.5b. Normal balloon pressure waveform characteristics include:
   - baseline between 0 mmHg and 2.5 mmHg
   - inflation artifact (overshoot)
   - deflation artifact (undershoot)

WARNING

If the balloon pressure waveform does not resemble a normal or acceptable waveform, take immediate action to correct a potentially unsafe condition. See Chapter 9 to troubleshoot the problem.

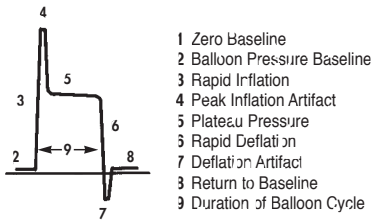


Figure 5.5a: Normal Balloon Pressure Waveform

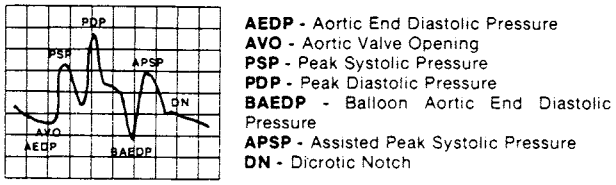


Figure 5.5b: Properly Timed Arterial Pressure Waveform

2. Monitor the balloon pressure waveform for helium leaks. If the pressure drops more than 10 mmHg, a helium leak probably exists and an automatic response alarm will occur. See Chapter 9 to troubleshoot the problem.
3. If you wish to compare the PDP of the patient to the BPW plateau, you may use the cursor key.

   A. Position the cursor line on the BPW plateau (flat portion - E)

   B. Note cursor measurement

   C. Compare to PDP

Proper IAB sizing, volume and operation may be assessed if the PDP and BPW are within 20 mmHg or *less* of each other.

Maintaining Balloon Pumping

The A*CAT*®1 automatically adjusts to heart rate variations and detects and tracks arrhythmias. In most cases, maintaining balloon pumping consists simply of monitoring IABP functions and responding to alarms.

WARNING

This device is frequently used in acute stages of cardiac failure. The clinician must be prepared to change trigger modes to optimize signal recognition, and utilize pharmacological, respiratory, temporary pacing, and other support measures to help stabilize the patient.

WARNING

If balloon pumping is interrupted and cannot be continued within 15-30 minutes, connect a 50/60cc syringe to the balloon connector and **inflate and deflate the balloon manually.** Thrombus formation may result from blood becoming trapped in the folds of a dormant balloon.

1. Check each of the following at least once an hour:
   - ECG leads: ECG electrodes should be changed at least every three days to prevent the gel from drying out.
   - Trigger source: ECG waveform shows prominent R-wave, no baseline wandering and consistent white overlay. Heart icon and selected trigger mode key flash with each beat.
   - Timing: AP waveform indicates optimum inflation and deflation points.
   - Balloon inflation volume: If the balloon volume has been decreased to less than 70% of the full volume for any reason, pump the balloon at maximum volume for at least five minutes every hour.
   - Balloon pressure: Normal or acceptable waveform is displayed.
   - Hemodynamic data: Check data displayed on the LCD.
   - Helium supply: LCD bar graph display shows at least l00psi.
   - Alarms: No alarms are displayed on LCD.
2. Respond to alarms as soon as possible. Safe IABP operation requires that you:
   - Give immediate attention to alarms that stop pumping
   - Follow the corrective steps specified in the alarm message
   - Save the recorder strip (if available) to aid in diagnostic troubleshooting
   - Maintain the alarms in the ALARMS ON condition
   - press the ALARM RESET control key to acknowledge the alarm and silence the audio tone

WARNING

Do not ignore alarm messages. **Do not** turn off alarms except for brief periods while correcting an alarm condition. After an alarm condition has been corrected, use the ON control key in the ALARMS section of the keypad to re-enable the alarms.

The OFF control key, in the ALARMS section of the keypad, disables the A*CAT*®1 diagnostic alarms while you test and troubleshoot the system. Alarms should be disabled only for brief periods of time to correct alarm conditions. ***The alarms should be ON during normal operation.*** *In rare cases, when a patient's EGG and AP waveforms are so poor that the* ACAT®1 *alarms frequently, you may wish to operate the* ACAT®1 *in the ALARMS OFF mode until the patient is stabilized. To engage ALARMS OFF, you must press the OFF control key once and then select the time period you want the alarms to remain off using the multi-function keys.*

Note: ***FLASHING LED ON ALARMS OFF CONTROL KEY AND A*** ***SYMBOL INDICATES THAT THE ALARMS ARE DISABLED. A warning message "ALARMS OFF" is displayed continuously above the ECG trace when alarms are off.***

Use the SHOW/HIDE STATS key to see how long the alarms are disabled for. You can also adjust the volume of the audio alarm tone using the AUDIO SETUP multi-function keys.

Note: *If the pump shuts down for any reason, note the time and call hospital personnel responsible for* ACAT®1 *maintenance for assistance. Switch to another IABP console if necessary. See Chapter 9 if you require additional information to correct an alarm condition.*

Freezing and Recording Waveforms

At any time during IABP operation, you can freeze the LCD or use the strip chart recorder to record waveforms and hemodynamic data.

Freezing the display

1. To freeze the LCD, simply press the FREEZE control key located in the DISPLAY section of the keypad. The waveforms will become stationary.
2. To return to moving waveforms on the LCD, press the FREEZE control key again.

Using the strip chart recorder

1. The preset strip recorder speed is 25mm/second. If you wish to change the speed to 50mm/second, simply press RECORDER SETUP multi-function key, then the SWEEP SPEED 9 or (control key in the RECORDER section.
2. The strip recorder will automatically print the ECG and AP waveforms. If you wish to record different waveforms, press the appropriate control keys until the desired selections are highlighted.

Note: Waveforms and sweep speed selected will be displayed in the status area of the display.

If you select only one waveform, the strip chart recorder will print one waveform using the full width of the recorder paper.

3. Press the ON/OFF control key, located in the RECORDER section of the keypad to print:
   - the waveforms you selected
   - the patient's hemodynamic data
   - current alarm messages
   - trigger mode
   - ECG lead
   - the date and time
   - assist ratio
   - balloon volume
   - timing settings

   Note: *Certain alarm conditions will automatically activate the strip chart recorder to print approximately the last seven seconds of patient data. Save this strip to aid in diagnostic troubleshooting. If the recorder is operating at the time of the alarm, it will automatically print the balloon pressure and AP waveforms.*
4. When you wish to stop the strip chart recorder, press the ON/OFF control key again.
5. If you wish to pre-program the recorder for automatic printing, press the RECORDER SETUP multi-function key and select TIMED RECORDING. Available intervals are 2, 15, 30, 60 minutes and 2 or 4 hours.

Weaning the Patient

Hours or days of IABP may result in some degree of dependence. The patient should be weaned from IABP according to your hospital policies and procedures. These instructions are guidelines only.

There are two methods of weaning which may be used independently or in conjunction with one another. Weaning can be accomplished by decreasing the frequency and/or volume of balloon inflation. Weaning by decreasing the frequency is accomplished by decreasing the frequency of assistance from one balloon inflation per cardiac cycle to 1:2, 1:4, and 1:8. Weaning can also be accomplished by decreasing the volume delivered to the balloon.

Weaning by decreasing the frequency:

1. Press the right 3 arrow ASSIST key in the ASSIST RATIO section of the keypad to set the assist ratio from 1:1 to 1:2.
2. As the patient condition warrants, decrease the assist ratio to 1:4, then 1:8. This is accomplished in the same manner as described in Step 1.

   IT IS RECOMMENDED THAT THE ASSIST RATIO BE RETURNED TO 1:1 FOR APPROXIMATELY FIVE MINUTES EVERY ONE TO TWO HOURS TO MINIMIZE THE RISK OF THROMBUS FORMATION WHEN THE ASSIST RATIO IS SET AT 1:8.

If the patient's condition indicates dependence, consider returning to a 1:1 assist ratio. If the patient's clinical condition shows signs of deterioration, terminate weaning and resume pumping at a 1:1 assist ratio.

Weaning by volume:

1. Press the PUMP OFF key.
2. Press the BALLOON VOLUME control key. Decrease the volume delivered to the balloon by pressing the down arrow multi-function key. Volume can be precisely adjusted in 0.5cc increments when decreasing the volume, and 2cc increments when increasing the volume.
3. A recommended procedure for volume weaning is as follows:

   Reduce the IAB volume 10% for 4-6 hours (90%, 80%, 70%* of full volume in 1:1 assist ratio). Resume pumping by pressing the PUMP ON key.

* Do not reduce the volume delivered to the balloon less than 2/3 (70%) the capacity of the balloon, i.e. a 40cc IAB should not have the volume reduced to less than 28cc. This is done in order to decrease the risk of thrombus formation. Also, when weaning by volume, it is recommended that the pump be returned to full volume for five minutes every one hour.

An option to consider would be to return the IAB to full volume and follow the recommendations for weaning by decreasing frequency.

General recommendations when weaning:

1. Monitor the patient's hemodynamic data to establish a baseline for analysis of response to weaning, and carefully monitor the patient during weaning.
2. Throughout the weaning period, monitor the patient's vital signs including but not limited to:

   • ECG
   • Heart rate
   • Blood Pressure
   • Urine output
   • Mentation
   • Distal perfusion
   • Cardiac output/index
3. When the patient no longer requires IABP support, press the OFF key in the PUMP STATUS section of the keypad to stop pumping, then remove the IAB according to your hospital policies and procedures, as well as IAB manufacturer's recommendations.
4. After each use, clean and disinfect the A*CAT*®1 and its accessories and perform the Operational Checkout Procedure. Section 8.1 of this manual contains instructions for both of these procedures.

A*CAT*®1 Transport

The A*CAT*®1 control system is self-contained and can run on battery power with full operational capabilities. A fully charged battery will power the A*CAT*®1 for a minimum of 120 minutes or 240 minutes if an optional second battery is installed. The A*CAT*®1's design allows for easy transport by utilizing a one body system that does not require any disassembly of the unit prior to transport. The A*CAT*®1 is always ready to go where ever and whenever it is needed.

WARNINGS

When transporting IABP dependent patients, anticipate the need for alternate power sources. Breakdown of vehicles, elevators, etc. may cause unexpected delays in reaching your destination AC power source. **Do not** attempt to transport if the "BATTERY CHARGED" LED is not illuminated. The A*CAT*®1 should not be used in conjunction with an AC power generator.

When transporting an IABP patient, move the patient and the A*CAT*®1 simultaneously to prevent stress on the balloon catheter and connector.

1. Before transporting an IABP dependent patient:
   - Make sure the patient's condition is sufficiently stable to withstand transportation.
   - The ECG signal should come from a patient cable, not a monitor.
   - The AP signal should come from a direct transducer, not a monitor.
   - Check battery charge status on the LCD for message "CHRG BAT: HI" prior to disconnecting from AC power source.
   - Check traffic conditions (distance, traffic, routes, etc.) to make sure the A*CAT*®1 will not be without AC power for more than 120/240 minutes during transport.
   - The vehicle should:
     – provide accessible entry and egress
     – provide adequate working space around the A*CAT*®1 – be equipped with oxygen, suction, monitors, defibrillators, respirator or ventilator capabilities, IV supplies and other forms of support
     – allow the patient and console to be tied down appropriately
     – provide access to the patient for routine care
     – be equipped with an inverter
     – be electrically safe
   - Assure that the transport team is trained to provide IABP support to the patient.
   - Arrange for police escort, if needed.
   - Confirm that the receiving hospital has compatible connectors, tubing, transducer cables, etc., for the Intra-Aortic Balloon catheter.

Note: *To be confident that you are prepared for situations that may occur during transport, practice one or more simulated moves before transporting an actual patient. Include difficult conditions in your simulations.*

2. Notify the receiving hospital of your estimated time of arrival.
3. If you are using air transport, mount the A*CAT*®1 as follows:
   A. Place the separate aircraft lock down bracket into the brown line track system on the aircraft. This is done by simply extending the pull-out arms to the desired length, place the bracket into the brown line track system, lift up the red aircraft lock lever and either pull or push the bracket until it locks in place.
   B. Reach under the center left of the lock down bracket and pull down on the locking pin. Rotate it a 1/4 turn to retain it in the unlocked position. Roll the A*CAT*®1 onto the aircraft lock down bracket. The A*CAT*®1 will self-align itself onto the bracket. Push until the unit locks in place. Turn the locking pin ring 1/4 turn to place it back to its locked position. The system is now secured for air transport.
   C. To remove the A*CAT*®1 from the bracket, simply reach under the bottom left front of the bracket pull down on the locking pin. Rotate it a 1/4 turn to retain it in the unlocked position. Pull the A*CAT*®1 off the aircraft lock down bracket and you are ready to go.
   D. The aircraft lock down bracket may be either left in the aircraft or removed and stored after use. To remove the aircraft lock down bracket, lift up the red handle to its upright position. The handle is located in the center of the bracket. Push or pull the bracket until it is free from the brown line track, and lift out.

   The FAA must approve aircraft to carry medical equipment. Arrow International, Inc. clinical support specialists and sales personnel can help you set up flight programs.
4. If you are using ground transport, mount the A*CAT*®1 as follows:
   A. Pick up the A*CAT*®1 by utilizing any of the handles located in both the front and rear of the unit, and place it into the ambulance.
   B. Locate the unit in it's desired location and lock all four casters by pushing down on the caster tabs.
   C. Strap the unit securely in place to the ambulance using standard tie-down straps. The system is now secured for ground transport.
5. During transport, operate the A*CAT*®1 as usual. Use AC power whenever possible to avoid the possibility of discharging the battery.

   Arrange the A*CAT*®1 control module and pump module to maximize your working space and LCD visibility during transport: you can lift up the control module at an angle, or remove the control module from the pump module (to allow for convenient viewing and positioning during transport). To do this, refer to the instructions provided in section 3.1.

CAUTION: Transport may involve high noise environments. In some environments, audible alarms may not be heard by the operator. Therefore, it is highly recommended that the operator have clear visibility of the LCD in transport situations since alarms are displayed on the LCD when they occur.

WARNING

Do not transport the A*CAT*®1 with the control module in the upright position. The module must be positioned down, flat to the pump module prior to transport, or the control module may be removed from the pump and carried.

6. When you have arrived at your destination, dismount the A*CAT*®1 as follows:
   - Remove the A*CAT*®1 from the floor mount.
   - Lift the A*CAT*®1 out of the aircraft/ambulance and place on the ground.
7. At the receiving hospital, establish baseline hemodynamic data just before and immediately after console exchange.

Note: *When the ACAT is running in battery, a warning message "ON BATTERY" is continuously displayed above the ECG trace. This message will clear when AC power is re-established.*

The A*CAT*®1 in the Operating Room or Catheterization Lab

The A*CAT*®1 may be used pre-operatively or for emergency intra-operative support (See "The A*CAT*®1 in Emergency Conditions."). Important operating considerations are listed below.

WARNING - EXPLOSION HAZARD

An explosion hazard exists with this system. **Do not** operate the A*CAT*®1 IABP System in the presence of flammable anesthetics or other gases.

WARNING

Do not use oxygen or any drive gas other than USP helium.

1. If the patient arrives with the A*CAT*®1 already pumping, confirm that the ECG cable is properly placed and that a clear AP waveform is displayed.
2. Keep the ECG electrodes and patient cables out of the sterile field. (see Fig. 5.7)
3. Use extra care in placing ECG electrodes. Place electrodes on the shoulder points or where people cannot easily touch them. If possible, cover electrodes with Steri-Drape®[1] to prevent the electrodes from getting wet (thereby losing contact).
4. Make sure that alternate ECG leads are available in case the triggering signal is lost with the initial lead. If possible, confirm in advance that all ECG leads yield clear, useful waveforms.
5. Never rely on only one trigger mode. Be prepared to change trigger modes as required.
6. During catheterization, press PUMP STNDBY to deflate the balloon whenever a guidewire or catheter is passed by the balloon. This is especially important in the presence of severe atherosclerotic disease. Press PUMP ON to restart pumping.

   Note: *If the* A*CAT*®1 *is left in STNDBY for longer than 3 minutes a Standby Alarm is issued. Press the PUMP STNDBY key twice to disable this alarm indefinitely.*
7. Remember that the ESIS circuit is designed to minimize interference but cannot totally eliminate it. If you cannot achieve a consistent ECG signal in spite of ESIS filtering, consider using the ART PRESS trigger mode. Minimize interference by:
   - Adequately preparing the skin prior to electrode placement
   - Placing electrodes on the frontal or posterial surface
   - Placing the active electrodes equidistant from the surgical site
   - Placing the cautery ground plate directly under the surgical site
   - Keeping ECG cables far away from and at right angles to electrosurgery cables
   - Positioning the ESU at right angles to the operating table
   - Using the lowest ESU settings necessary for cautery and coagulation
   - Avoiding unnecessarily high ECG gain control settings

[1] Steri-Drape® is a trademark of the 3M company

WARNING

Pacer triggering is not recommended during operation of Electro-Cautery Devices.

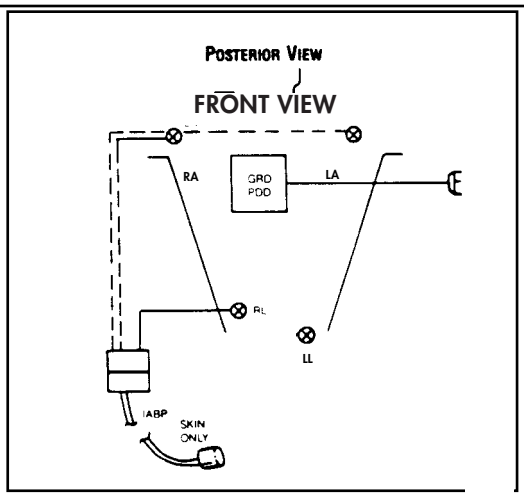


Figure 5.6: Placement of ECG and ESU Cable

Note: An optional 3 lead (IAA-04303) or 5 lead (IAA-04305) NDM/ConMed back pad electrode and cable are available for use in these environments. The electrode may be placed on the back or thigh. This produces a non-diagnostic R wave, but is generally adequate for triggering. See section 8.2 for ordering information.

The A*CAT*®1 in the Intensive Care Unit

In the ICU, it is important to help the patient and staff feel as comfortable as possible with the presence of the A*CAT*®1.

1. If possible, it may be desirable to minimize the number of lines to the patient by using ECG and AP monitor signals. However, direct patient signals are preferred.
2. Do not elevate the head of the bed greater than 25° to 30°.
3. If possible, turn the patient every two hours.
4. Reassure the patient that the sounds coming from the A*CAT*®1 are normal.

The A*CAT*®1 in Emergency Conditions

In emergency situations, it is critical to initiate counterpulsation quickly. You should be familiar with the operating procedures described in Section 5.1. If possible confirm that ECG and AP monitor outputs are compatible with the A*CAT*®1 before an emergency arises.

Follow the instructions below to initiate pumping rapidly.

1. Plug in the power cord, then press the power switch located on the patient interface panel on the front of the console.
2. Connect ECG and AP signals from bedside monitors.

   Note: *Remember that it may not be possible to place electrodes intra-operatively. If electrosurgical units are present, consider using the ART PRESS trigger mode.*
3. Connect the balloon to the A*CAT*®1 balloon connector on the front of the console.
4. Press the ON control key in the PUMP STATUS section of the keypad to initiate counterpulsation.
5. Use the inflate/deflate control keys to adjust timing.
6. After the patient has been stabilized, apply ECG electrodes and connect the patient ECG cable to the A*CAT*®1 if transport is required.

Arterial pressure signals to the A*CAT*®1 may come from transducers or from monitors. A reuseable pressure transducer should be calibrated before initiation of counterpulsation. Although mercury manometer calibration is not required for disposable transducers, it is recommended for accuracy, especially with reusable strain gauge transducers. A monitor, on the other hand, need not be zeroed or calibrated if its output is compatible with the A*CAT*®1 (100 mmHg/volt).

Regardless of what type of input signal you have, you may wish to alter the display range for a pressure waveform. The preset range on the LCD is 50-150mmHg for the AP waveform.

This chapter provides instructions for calibrating transducers and for adjusting the waveform display range.

The contents of this chapter include:

6.1: *Calibration of Transducers* 6-3

Transducer Calibration 6-3
Changing the Display Range 6-4

Transducer Calibration

You must calibrate reuseable transducers prior to initiating counterpulsation. You should also recalibrate the transducer during patient use according to your hospital's protocol to correct drifts that may occur over time. Connect the transducer to the A*CAT*®1 console (see Section 5.1) before calibration.

Steps Required for Calibrating a Strain Gauge Transducer (Reusable)

1. Using a syringe, place 1cc of sterile water on the transducer diaphragm.
2. Screw the transducer dome, used for calibration, onto the transducer diaphragm.
3. Attach one end of the transducer dome to a manometer via the luer connectors.
4. Attach a hand bulb to the other luer lock.
5. Make sure that the transducer is attached to a vertical support rod or IV pole and is at the same height as the patient's right atrium.
6. Turn the transducer until the manometer connection is at the top. The manometer connection stopcock should be in a vertical position.
7. Open the manometer connection stopcock to the air. Press AP SOURCE SELECT. The multi-function keys will now show the AP Scaling, ZERO and calibration (CAL) functions. Press the ZERO control key. Observe the message Arterial Pressure Zero'd.
8. Select CAL. This will display sens> sens<.
9. Use the manometer to pressurize the AP transducer to 100mmHg. Press the UP or DOWN arrow keys to increase or decrease the sensitivity until the number on the LCD corresponds to the manometer level, if other than 100mmHg.
10. Release the manometer pressure, close the manometer connection and open the transducer to the patient.
11. Disconnect the manometer from the manometer connection.
12. Prior to patient monitoring, remove the dome used for calibration and replace with a new sterile dome.

    CAUTION: Follow the manufacturer's instructions to connect the heparinized fluid source to the constant flush unit. All pressure tubing, stopcocks and connections must be filled completely with fluid and free from air bubbles before proceeding with calibration.

13. Flush system of air, rezero and check calibration factor prior to patient use.

NOTE: If the system has been incorrectly calibrated, press CAL then AUTO to return to the preset system calibration (100 mm/v).

Steps Required for Zeroing a Disposable Transducer

1. Press AP SOURCE SELECT.
2. Multi-function keys will now display AP scaling, zero and calibration functions.
3. Open transducer to air.
4. Press ZERO. Message area on display will indicate "Zero'd" or Failed to Zero" message.

To change the display range, select AP SCALING or proceed to the instructions below.

Changing the Display Range

The A*CAT*®1 allows you to make changes in the amplitude of pressure waveforms. For example, a patient with a PSP and PDP exceeding 150mmHg will not have peak pressures visible on the AP waveform (50-150mmHg is the preset amplitude value). By changing the waveform display range to 50-200mmHg the full waveform can be seen. For a patient with EDP less than 50mmHg, the display range can be changed to 0-50mmHg or 25-100mmHg to display the entire waveform.

- Select AP SCALING in the multi-function keys. Press the key under the desired scale. New settings will be highlighted in reverse video.
- The recorder scale also changes with the changing of the AP DISPLAY SCALE.

Display Scale Setting	Dual Trace	Single Trace
0 -100mmHg	25.0mmHg/Div	12.5mmHg/Div
25 - 100mmHg	18.75mmHg/Div	9.375mmHg/Div
0 - 150mmHg	37.5mmHg/Div	18.75mmHg/Div
50 - 150mmHg	25.0mmHg/Div	12.5mmHg/Div
0 - 200mmHg	50.0mmHg/Div	25.0mmHg/Div
50 - 200mmHg	37.5mmHg/Div	18.75mmHg/Div
50 - 250mmHg	50.0mmHg/Div	25.0mmHg/Div

The A*CAT*®1 IABP System has many built-in safety mechanisms. Diagnostic alarms alert you to certain console and catheter conditions that require your attention. It is very important to respond to these alarms promptly, especially those that involve pump shutdown. In addition, you must observe certain precautions while you operate the A*CAT*®1 IABP System to assure smooth operation and patient safety. Follow the Warnings and Cautions listed in this chapter carefully. They are also cited in other sections as appropriate.

The A*CAT*®1 IABP System is designed to maximize patient and user safety. However, it is a high voltage system. This chapter also describes the hazards associated with the use of the A*CAT*®1. Accidents are preventable. Please observe the appropriate precautions. Section 7.3 describes what to do in case of system malfunction or pump shutdown.

The contents of this chapter include:

7.1: ***Warnings and Cautions for the ACAT®1*** **7-3**

7.2: ***Hazards Associated with the ACAT®1*** **7-8**

7.3: ***System Malfunction and Pump Shutdown*** **7-9**

The key precautions to observe during Intra-Aortic Balloon Pumping are briefly summarized below as reminders. These statements are cited and explained throughout this manual as appropriate. The instructions in this manual in no way supersede established medical practices or staff preferences concerning patient care. Always observe "best practice" as determined by the medical community. The following precautions should be observed:

WARNING (pages 2-3 and 8-4)	An electric shock hazard may exist with this system. Always operate the A*CAT*®1 from a 3-wire hospital-grade AC and electrical system with a separate ground. **Do not** remove the round grounding pin from the system's plug. **Do not** use a 3-wire to 2-wire adapter to avoid the system's ground. Do not place fluids in the storage compartments on top of the A*CAT*®1.
WARNING (pages 2-3 and 8-4)	The biomedical engineering department or other qualified person should verify the integrity of the AC power system ground. In addition, the ground should be checked periodically.
WARNING (pages 2-3 and 5-3)	The A*CAT*®1 IABP System requires a trained operator who has read and understands all sections of this manual prior to using the A*CAT*®1 IABP System. Only medical personnel trained in the use of IABP devices and acting under a physician's orders should operate this system.
WARNING (pages 3-7 and 5-25)	DO NOT transport the A*CAT*®1 with the control module in the upright position. The control module must be positioned down, flat to the pump module prior to transport, or the control module may be removed from the pump and carried.
WARNING (pages 3-19 and 5-10)	The INTERNAL trigger mode should be used only if the patient has no myocardial activity and/or ventricular ejection. You must press the INT control key in the TRIGGER MODE section of the keypad twice if you wish to operate the A*CAT*®1 IABP in the INTERNAL trigger mode. An audible alarm will sound to alert you that an ECG is present when INTERNAL is selected. A warning message "INTERNAL" is displayed continuously above the ECG trace when INT is selected.
WARNING (page 3-28)	Alarms should be on at all times to insure safe operation. If alarms are suspended, the IABP should be continuously monitored by trained personnel. A warning message ALARMS OFF will be continuously displayed above the ECG trace when alarms are off.

WARNING (pages 3-54 and 5-13)	The operator must closely observe the effects of inflation timing on deflation timing whenever the settings are altered. Failure to do so may adversely impact the expected benefits of counterpulsation and have serious clinical sequelae.
WARNING (pages 3-54 and 5-13)	The operator must continuously monitor the patient's Arterial Pressure waveform whenever the deflation point is set beyond 100%.
WARNING (pages 4-8 and 5-26)	**Do not** use oxygen or any drive gas other than USP helium.
WARNING (page 5-5)	**Do not** use solvents (e.g., acetone or other degreasing agents) to prepare the skin. They may damage the IAB catheter or other plastic components of the system.
WARNING (page 5-6)	Be prepared to maintain IABP operation in critical situations by having a backup IABP System and extra helium bottles ready in case of system failure or helium depletion.
CAUTION (page 5-6)	**Do not** use electrodes after expiration date.
WARNING (page 5-10)	Arterial Pressure triggering is not recommended if the patient is in atrial fibrillation or has tachyarrhythmias. These conditions produce irregular Arterial Pressure waveforms.
WARNING (page 5-10)	With acutely ill patients, both the ECG and Arterial Pressure waveforms may be inadequate for triggering.
WARNING (page 5-10)	Certain monitors may process pacing signals and reinsert spikes that do not meet A*CAT*®1 criteria. In this case, the patient cable must be used to use pacer triggers.
WARNING (page 5-12)	A properly coded balloon connector should be used with all balloons, including those not manufactured by Arrow International. Using a balloon connector coded for a volume greater than that of the balloon can have serious clinical consequences. Verify balloon volume prior to operating the pump, as described in section 5.1.
WARNING (pages 5-12, 9-9 and 9-16)	If an IAB is suspected of being occlusive, do not reduce the IAB volume to less than 2/3 of the balloon's capacity. To prevent thrombus formation, pump the balloon at its maximum capacity for five minutes every hour. A smaller IAB volume should be considered.

WARNING (page 5-13)	**Do not** continue to move the inflation point to the left, even to increase PDP further. Early inflation can compromise systole.
WARNING (page 5-13)	**Do not** attempt to adjust timing based on ECG or Pacer waveforms. Inflation and deflation points should be set based on the Arterial Pressure waveform. Monitor this waveform to achieve optimum hemodynamic benefit.
WARNING (page 5-17)	If the balloon pressure waveform does not resemble a normal or acceptable waveform, take immediate action to correct a potentially unsafe condition. See Chapter 9 to troubleshoot the problem.
WARNING (page 5-18)	This device is frequently used in acute stages of cardiac failure. The clinician must be prepared to change trigger modes to optimize signal recognition, and utilize pharmacological, respiratory, temporary pacing, and other support measures to help stabilize the patient.
WARNING (page 5-18)	If balloon pumping is interrupted and cannot be continued within 15-30 minutes, connect a 50/60 cc syringe to the balloon connector and **inflate and deflate the balloon manually.** Thrombus formation may result from blood becoming trapped in the folds of a dormant balloon.
WARNING (page 5-19)	**Do not** ignore alarm messages. **Do not** turn off alarms except for brief periods while correcting an alarm condition. After an alarm condition has been corrected, use the ON control key in the ALARMS section of the keypad to re-enable the alarms.
WARNING (page 5-23)	When transporting IABP dependent patients, anticipate the need for alternate power sources. Breakdown of vehicles, elevators, etc. may cause unexpected delays in reaching your destination AC power source. **Do not** attempt to transport if the "BATTERY CHARGED" LED is not illuminated. The A*CAT*®1 should not be used in conjunction with an AC power generator.
WARNING (page 5-23)	When transporting an IABP patient, move the patient and the A*CAT*®1 simultaneously to prevent stress on the balloon catheter and connector.
CAUTION (page 5-25)	Transport may involve high noise environments. In some environments, audible alarms may not be heard by the operator. Therefore, it is highly recommended that the operator have clear visibility of the LCD in transport situations since alarms are displayed on the LCD when they occur.

WARNING (page 5-26)	An explosion hazard exists with this system. **Do not** operate the A*CAT*®1 IABP System in the presence of flammable anesthetics or other gases.
WARNING (page 5-27)	Pacer triggering is not recommended during operation of Electro-Cautery Devices.
CAUTION (page 6-3)	Follow the manufacturer's instructions to connect the heparinized fluid source to the constant flush unit. All pressure tubing, stopcocks and connections must be filled completely with fluid and free from air bubbles before proceeding with calibration.
WARNING (page 7-9)	Pump shutdown requires immediate staff action. Note the time and call knowledgeable maintenance personnel. If pumping cannot be restored within 15-30 minutes, manually inflate and deflate the IAB several times per hour to reduce the risk of thrombus formation. Consider removing the balloon. Arrow International recommends that you have a back-up IABP system available.
CAUTION (pages 8-1 and 8-12)	Panel covers should not be removed by anyone other than Arrow International Field Service Engineers or their authorized representatives. Shock hazards exist when the protective covers are removed.
WARNING (page 8-4)	A fully charged battery will power the A*CAT*®1 for a minimum of 120 minutes. To fully recharge a completely discharged battery, the system must be connected to AC power for about eight hours. Eighty percent of the battery's charge will be restored within four hours.
CAUTION (page 8-7)	**Do not** clean the A*CAT*®1 console while it is connected to a patient.
CAUTION (page 8-7)	Clean and disinfect using only those solvents listed. **Do not** use other solvents. Avoid acetone, phenol, ether or higher concentrations of formaldehyde. These chemicals can damage the console's finish and accessories.
CAUTION (page 8-7)	Examine the cable's outer casing carefully for perforations before cleaning. **Do not** soak a perforated cable. Have it repaired or replaced immediately.
CAUTION (page 8-7)	**Do not** submerge electrical connectors during disinfection. Secure a 3mm-thick polyethylene wrapping over the connector before cleaning. **Do not** use phenol-based cleaners. They cause cables to harden and crack. **Do not** allow cables to remain immersed in alcohol or other cleaning agents.

CAUTION (page 8-10)	High-pressure gas cylinders should be handled by trained personnel only.
CAUTION (page 8-12)	Use only the fuse type and rating specified. Call Arrow International's service number for assistance.
WARNING (page 9-6)	Do not turn alarms off except for brief period while correcting an alarm condition. After the alarm condition has been corrected, enable the alarms by pressing the ALARMS ON control key.
WARNING (page 9-7)	Any evidence of blood leakage within the IAB assembly warrants immediate IAB removal.
CAUTION (page 9-13)	ESIS is operational at all times, however, it is most effective when a three-lead or five-lead ECG cable is used.

All operators should be aware of the following hazards associated with use of the A*CAT*®1 IABP System. Follow appropriate precautions carefully to prevent accidents.

Explosion Hazard (page 5-26)

Do not operate the A*CAT*®1 IABP System in the presence of flammable anesthetics or other gases.

As with any electrical instrument, sparks may be formed when the ACAT®1 *is plugged in, turned on, etc. If this occurs in the presence of flammable gases, an explosion could result.*

Electric Shock Hazard (pages 2-3 and 8-4)

An electric shock hazard may exist with this system. Always operate the A*CAT*®1 from a 3-wire hospital-grade AC electrical system with a separate ground. **Do not** remove the round grounding pin from the system's plug. **Do not** use a 3-wire to 2-wire adapter to avoid the system's ground. Do not place fluids in the storage compartments on the top of the A*CAT*®1.

The biomedical engineering department or other qualified person should verify the integrity of the AC power system ground. In addition, the ground should be checked periodically.

The ACAT®1 *is a high voltage system. To prevent electric shock, it should be properly grounded and you should not remove the grounding pin or the* ACAT®1 *side panels.*

System Malfunction and Pump Shutdown

Specific patient states, operating conditions or pump malfunctions can cause shutdown of pumping action. The A*CAT*®1 has internal diagnostic mechanisms to notify you of console or catheter malfunctions. The possible causes and suggested corrective actions will be displayed on the LCD. It is important to pay attention to alarms and to respond immediately if the pump shuts down. If the pump shuts down, the balloon will deflate automatically. However, allowing a deflated balloon to remain dormant is hazardous. A deflated balloon does not provide valuable cardiac support to the patient and thrombus formation can occur if blood becomes trapped in the folds of the deflated balloon.

WARNING

Pump shutdown requires immediate staff action. Note the time and call knowledgeable maintenance personnel. If pumping cannot be restored within 15-30 minutes, manually inflate and deflate the IAB several times per hour to reduce the risk of thrombus formation. Consider removing the balloon. Arrow International recommends that you have a back-up IABP system available.

If a pump shutdown occurs, note the time and call hospital personnel knowledgeable in the maintenance of the A*CAT*®1. If repair and pumping cannot be accomplished within 15-30 minutes, use a 50/60 cc syringe to rapidly inflate and deflate the balloon several times per hour. This will reduce the risk of thrombus formation, but should be used only as an emergency procedure for short periods of time while awaiting the physician's arrival. The physician should consider removing the balloon. Arrow International, Inc. recommends that you have a back-up IABP system available in case of a pump shutdown.

Chapter 9 contains troubleshooting tables to help you identify and correct problems quickly. If you are unable to correct a problem with your system, call your Arrow International Representative or the Product Support Line for assistance.
(see section 2.1)

The A*CAT*®1 IABP System requires minimal service and care. Routine maintenance procedures should be performed regularly to optimize performance and reduce the likelihood of down-time. When a specific operational problem occurs, the trouble-shooting guidelines in Chapter 9 will help you quickly diagnose and correct the problem.

Operators should attempt only those maintenance procedures described in this chapter, and you should be familiar with the functions and layout of the A*CAT*®1 (as described in Chapter 3) before attempting these procedures. Other service procedures should be performed by qualified Arrow International, Inc. technicians only. This chapter provides service and ordering information for your convenience. Arrow International, Inc. service organization operates 24 hours a day.

CAUTION

Panel covers should not be removed by anyone other than Arrow International Field Service Engineers or their authorized representatives. Shock hazards exist when the protective covers are removed.

The contents of this chapter include:

8.1: *Routine Maintenance Procedures* **8-3**

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A*CAT*®1 System Maintenance Schedule

This schedule provides an outline of the frequency that Arrow International recommends the following routine maintenance and service procedures be performed. The procedures listed as being in the Operators Manual can be performed by the operator of the A*CAT*®1, the Biomedical Engineering department, or other qualified personnel. The procedures listed as being in the Service Manual should only be performed by Arrow International Field Service Representatives or by trained Biomedical Engineering personnel.

Manual	Section	Procedure/Frequency	Each Use	Weekly	Bi-Annually
Operator	8.1	Condensate Removal	X		
Operator	8.1	Cleaning and Disinfection	X		
Operator	8.1	Operational Checkout		X	
Operator	8.1	Battery Test			X
Service	6.1	Console Maintenance & Checkout			X
Service	6.1	Electrical Safety Test			X
Service	6.1	Functional Test			X

Operational Checkout

Arrow International recommends that you perform the Operational Checkout described below at weekly intervals to verify that the displays, pumping mechanism, controls and indicators are functioning properly. The system should also be checked prior to its anticipated use to allow sufficient time to correct any problem found.

If the A*CAT*®1 does not respond according to the guidelines below, repeat the steps to ensure that you have performed them correctly. If the faulty response continues, contact your Arrow International Field Service Representative for assistance.

1. Plug the power cord into an active, properly grounded AC outlet. When AC power is applied to the A*CAT*®1, the POWER INDICATOR LED on the front panel will illuminate.

WARNING - ELECTRIC SHOCK HAZARD

An electric shock hazard may exist with this system. Always operate the A*CAT*®1 from a 3-wire hospital-grade AC electrical system with a separate ground. **Do not** remove the round grounding pin from the system's plug. **Do not** use a 3-wire to 2-wire adapter to avoid the system's ground. Do not place fluids in the storage compartments on the top of the A*CAT*®1.

WARNING

The biomedical engineering department or other qualified person should verify the integrity of the AC power system ground. In addition, the ground should be checked periodically.

WARNING

A fully charged battery will power the A*CAT*®1 for a minimum of 120 minutes. To fully recharge a completely discharged battery, the system must be connected to AC power for about eight hours. Eighty percent of the battery's charge will be restored within four hours.

2. Press the power switch located on the connector panel of the unit. The power switch, LCD and the preset keypad LED's should illuminate.

   If "ON BATTERY" warning message is displayed, the A*CAT*®1 *may not be receiving AC power. Unplug the* A*CAT*®1 *and repeat steps 1 and 2 at another properly grounded AC outlet, or ask an electrician to check the AC outlets for power.*

   To check Flash Card, place card in recepticle and then power on. Settings now reflect user-defined setup.

4. Strip chart recorder:
   - Check to make sure that there is a full roll of recorder paper.

     If you are unsure how to do this, refer to the instructions for recorder paper installation in this chapter. If there is less than a full roll, install a new roll of recorder paper.
   - Press the ON/OFF control key in the RECORDER section of the keypad and allow the strip chart recorder to print for a few seconds, then press ON/OFF control key again to stop printing.
   - Observe the recorder strip. The correct date and time should be printed.

     If the date and time are incorrect, refer to CLOCK SET multi-function key description in Section 3.3 for instructions for correcting the date and time (this should be necessary only at Daylight Savings Time and on leap years).
5. Observe the helium supply reading on the LCD. It should read at least 100psi.

   If the display shows "HE 100psi" or less, see the instructions in this chapter to replace the helium tank.
6. Check for helium leaks:
   - Observe the helium supply reading on the LCD. Note any rapid pressure drops or variations.
   - Remove and replace the helium tank according to the instructions in this chapter. The helium supply reading should rise rapidly, then remain steady.
   - Observe the helium supply reading on the LCD again. Note any rapid pressure drops or variations.

   If you note any pressure variations after reinserting the helium tank, call your Arrow International Field Service Representative for assistance. (see section 2.1)
7. Select the INTERNAL trigger mode:
   - Press the INT control key in the TRIGGER MODE section of the keypad twice.
   - Observe the following warning message on the LCD above the ECG trace: "INTERNAL"

   If the internal rate display does not show 80, set the rate to 80 using the UP and DOWN arrows in the multi-function keys.

8. Depress the left L and R right arrows of the inflate/deflate control keys, located on the sides of the A*CAT*®1 LCD. As you depress the control keys, the white overlay on the green line at the top of the LCD and the green bar at the bottom of the LCD will change. Note that the numbers change corresponding to the new Inflate/Deflate settings.
9. Connect an Arrow International hydraulic load simulator (P/N IAT-00025) to the BALLOON CONNECTOR outlet located next to the power switch on the front of the A*CAT*®1 console.

   This simulator does not come with the A*CAT*®1 *IABP System. You can order it as an accessory. See Section 8.2 for ordering information.*
10. Observe the volume display (VOL XX.X CC). The display will show the volume of the balloon connector.
11. Test the control keys:
    - Press the STNDBY key in the PUMP STATUS section to purge the helium lines.
    - Press the ON key in the same section. The third channel on the LCD should show a moving balloon pressure waveform.
    - Press the FREEZE control key. The balloon pressure waveform should become stationary.
    - Press the FREEZE control key again. The balloon pressure waveform should move as before.
    - Press the OFF control key to stop the pump and vent the helium system.
12. Press the power switch to turn off the A*CAT*®1.
13. Disconnect the simulator that you connected to the BALLOON CONNECTOR outlet in step 9. The volume will decrease to 5cc.
14. If the A*CAT*®1 IABP System will not be used within four weeks, follow the System Shutdown instructions in this chapter.

    If at any time during the Operational Check-out Procedure steps cannot be completed and a pump malfunction is suspected, call your Arrow International Field Service Representative for assistance. (see section 2.1)

Cleaning and Disinfection

Clean the A*CAT*®1 console, accessories and cables after each use.

CAUTION

Do not clean the A*CAT*®1 while it is connected to a patient.

1. Turn off the power and unplug the A*CAT*®1's power cord.
2. Use a soft cloth dampened with mild soap and water or 70% isopropyl alcohol to remove dust and dirt from the exterior of the console. To disinfect the console, use a 70% solution of carbolic acid (Lysol®[1]), methyl alcohol or isopropyl alcohol.

CAUTION

Clean and disinfect using only those solvents listed. **Do not** use other solvents. Avoid acetone, phenol, ether or higher concentrations of formaldehyde. These chemicals can damage the console's finish and accessories.

3. Clean and disinfect accessories after each use according to the manufacturer's instructions. Cold-soak accessories in zephiran chloride. Soak blood-stained cables in hydrogen peroxide or a bleach solution for a few minutes.
4. Clean patient cables and leads with a bactericidal agent or alcohol. Dry them thoroughly.

CAUTION

Examine the cable's outer casing carefully for perforations before cleaning. **Do not** soak a perforated cable. Have it repaired or replaced immediately.

CAUTION

Do not submerge electrical connectors during disinfection. Secure a 3mm-thick polyethylene wrapping over the connector before cleaning.

Do not use phenol-based cleaners. They cause cables to harden and crack. **Do not** allow cables to remain immersed in alcohol or other cleaning agents.

5. Plug the power cord back into an active, properly grounded AC power source.

[1] Lysol® is a registered trademark of Lehn & Finks Products.

Condensate Removal

Check the condensate bottle with every use and empty whenever it becomes full. This can be done while pumping. Follow handling procedures for biohazardous waste removal.

1. Open the helium compartment to find the condensate bottle (behind the He tank in the recess).
2. Lift the black locking handle to the left of the He tank, then pull the bottom of the He cannister toward you.
3. Pull out the bottle (keeping it upright) and unscrew the cap.
4. Empty the bottle. Follow bio-hazardous material handling procedures for your hospital.
5. Screw on the cap, replace the bottle and close the compartment.

Figure 8.1: The Condensate Collection Bottle

Figure 8.2: The Condensate Collection Bottle Behind the Helium Tank

Recorder Paper Installation

The recorder uses rolls of blank 50mm thermal-sensitive paper. See Section 8.2 for ordering information.

1. Verify that the strip chart recorder is off.
2. Follow the paper loading instructions listed below.
   - Push the latch at the top of the recorder to open paper compartment. Gently remove the old roll.
   - Place the new roll of recorder paper in the compartment. The paper should feed out from under the bottom of the roll. Feed some paper out towards the front across the rubber roller.
   - Close the door.

Figure 8.3: Strip Chart Recorder

3. Press the ON/OFF control key to obtain a recording. You should see lines and print on the paper. Press the ON/OFF control key again to stop recording.

   Note: *If waveforms are not printed, the paper has been inserted backwards. Repeat step 2, reversing the direction of the paper roll.*

CAUTION
High pressure gas canisters should be handled by trained personnel only.

Helium Tank Replacement

The helium tank should be replaced when "LOW HELIUM SUPPLY" appears on the LCD (the helium supply has fallen to 100psi). Use only 500psi disposable or 2000 psi disposable/refillable USP helium canisters. See Section 8.2 for ordering information.

Note: *The ACAT®1 provides automatic scaling of the He bar graph, depending on the amount of He in the tank.*
When the He level is above 500 psi the display scale will be 2000 psi. Each division is 500 psi. When the tank pressure is below 500 psi the bar graph will rescale to 500 psi. The 500 value will be displayed in yellow to indicate a different scale. Each division is 125 mmHg. The bar graph changes to red when the He level is less than 125 mmHg the bar graph will go to black when less than 20 psi are in the tank. The tank should be changed when the bar is in red.
Press HOME and SHOW STATS to view the He tank pressure in psi.

1. If the A*CAT*®1 is in use, press the OFF control key in the ALARMS section of the keypad and select the F1 key for 10 minutes off. This will temporarily disengage the automatic refill system. After completing the tank replacement procedure, press the ON control key in the ALARMS section of the keypad to re-engage the automatic refill system.
2. Open helium compartment door.
3. Identify tank.

   500 psi disposable tank -

   a. Lift latch.
   b. Pull bottom of tank toward you.
   c. Unscrew tank and dispose
      Note: If 2000 psi tank will be installed, remove 500 psi tank yoke adaptor (see section 2 for details) then follow instructions for 2000 psi tank installation.
   d. Screw in a new cylinder by inserting the He tank threads into the regulator adapter.
   e. Verify He tank pressure on display.
   f. Push the bottom of the He tank in and secure with the latch.
   g. Close helium compartment door.

2000 psi tank -

a. Close tank valve on top of tank.
b. Loosen T-handle on regulator yoke.
c. Remove tank.
d. Reinsert new 2000 psi tank (insure He washer is in place) and align tank to locating pins.
e. Tighten T-handle.
f. Open tank valve.
   Note: If you desire to replace 2000 psi tank with 500 psi tank, the 500 psi regulator yoke adapter must be installed in the regulator yoke. Then follow the instructions for installing a 500 psi disposable tank.
g. Close helium compartment door.
h. Verify helium level.

Figure 8.4: Helium Tank Installation with Disposable Tank

Figure 8.5: Helium Tank Installation with Refillable Tank

Fuse Replacement

The A*CAT*®1 has two fuses located in the pump module. These should be changed only by Arrow International Field Service Engineers or trained personnel. See Section 8.2 for ordering information. Part numbers for the fuses can be found in Section 2.1.

CAUTION

Use only the fuse type and rating specified. Call Arrow International's service number for assistance.

CAUTION

Panel covers should not be removed by anyone other than Arrow International Field Service Engineers or their authorized representatives. Shock hazards exist when the protective covers are removed.

To change the fuses (if necessary), remove the AC power cord as described in Section 2.1, use a small flat blade screwdriver to press on the fuse holder locking lever and remove the fuse drawer which carries two fuses. Remove fuses from the drawer, insert new fuses into the drawer and install fuse drawer back into place. Press the drawer in until it clicks indicating that it has locked into position. Reinstall the power cord as described in Section 2.1.

System Shutdown

If the A*CAT*®1 will be idle for four weeks or more, shut down the system as follows:

1. Press the power switch to turn off the power.
2. Remove the disposable helium tank or turn off disposable/refillable tank (see instructions in this section).
3. Empty the condensate bottle (see instructions in this section).
4. Store all required cables with the console.

   Note: *Leave the power cord connected to an AC power supply to maintain a full charge on the battery. The system automatically prevents overcharging.*

Sealed Lead Acid Battery Maintenance

The A*CAT*®1 System utilizes one, or two with optional second battery installed, sealed lead acid batteries to power the system during times when AC power is not available. The batteries are considered maintenance free, meaning that they are sealed to prevent leakage and they do not require the operator to add any materials such as water or electrolyte. However, routine care of these batteries should be taken to insure their safe operation and maximize their usable lifespan. The following steps outline the basic procedures that should be followed for proper sealed lead acid battery care.

The batteries are labeled with the following information:

-Refer to the manual symbol "!"
-battery symbol
-recycling symbol
-Arrow part number for the battery
-lead contents in %
-disposition instructions

1. The battery should be maintained at full charge whenever possible. Arrow International recommends that the A*CAT*®1 IABP System be kept plugged into a proper AC receptacle whenever possible including time when the unit is in storage or not in use. The power indicator will illuminate when AC power is present. The batteries should not be stored in a discharged state.
2. If it is desired to clean the case of the batteries, use only a water dampened cloth. Solvents such as paint thinners, adhesive removers, and petroleum based materials should never be used. The case of the batteries is constructed of high impact ABS plastic resin and could be damaged by such solvents.
3. Visually inspect the batteries for signs of physical damage such as leaks or cracks in the case. Any physically damaged batteries should be replaced immediately. Never attempt to repair or dismantle any battery. If there is accidental body contact with battery electrolyte, flush the contacted area with liberal amounts of clean fresh water and seek medical attention.
4. Never short circuit the terminals of the battery.
5. The A*CAT*®1 IABP System has an automatic battery voltage level monitor which shuts down the system should the voltage fall below 10 volts. Discharging the batteries below 10 volts will provide very little additional running time of the A*CAT*®1 IABP System and could possibly damage the batteries. The batteries should not be discharged below this level.

6. Heat is detrimental to batteries. Batteries should always be stored away from sources of heat whether in the unit or outside. The batteries contain a safety vent which is designed to release gasses if the temperature of the batteries exceeds 125 degrees Fahrenheit. If the vent has been actuated the batteries should be replaced.
7. With proper care, the batteries used by the A*CAT*®1 IABP System should provide many years of trouble free service. It is not required that these batteries be replaced based solely on the basis of their age. However, to insure the highest level of reliability, Arrow International recommends that the batteries be replaced after three years of service. As the batteries age, it is important that their performance be periodically checked to insure that they will perform as intended. It is recommended that a load test, as outlined in this manual, be performed by qualified service personnel at six month intervals to ensure battery capacity and usability. Any time that the batteries do not pass the load test they must be replaced.

   If it is not possible to perform the load test, or if the batteries' capacity and usability cannot be verified for any reason, the batteries must be replaced after three years of use.
8. If the optional second battery is installed and replacement of the batteries is required for any reason, always replace the batteries in pairs and with the proper type and rating of battery and follow battery replacement procedure outlined in this manual. Never replace only one battery.
9. Sealed lead acid batteries are manufactured of highly recyclable materials and should be recycled whenever possible. Never dispose of batteries in fire. Doing so could result in possible rupture or explosion of battery. **For lead acid battery disposition instructions contact your local Government Authorities or Arrow International local representative.**

Battery Load Test

1. Plug the A*CAT*®1 System into a proper AC outlet for at least four hours to charge the system's internal batteries.
2. After fully charging the system's internal batteries, measure the battery voltage at the battery terminals. The battery voltage should be 13 volts DC±0.1 volts to perform this test. If the battery voltage is below this level, the internal batteries are not fully charged. Allow additional charging time before beginning this test. Repeat step 1. After the additional charging time has passed, measure the battery voltage again. If the battery voltage is at least 13 volts DC±0.1 volts, proceed to step 3. If the battery voltage is still not at this level, after two battery charging cycles, a possible problem may exist in the charging/battery system. Power down the A*CAT*®1 and notify qualified service personnel.
3. Attach an Arrow Hydraulic Load Simulator or other proper load device to the balloon connector of the A*CAT*®1. Install a helium cylinder with at least 100 psi of pressure. Select INTERNAL TRIGGER by pressing the INTERNAL TRIGGER key twice. Press PUMP ON to initiate pumping. Disconnect the A*CAT*®1 from AC power by removing the AC plug from the wall receptacle.
4. After a few seconds an alarm indicating that the A*CAT*®1 System is now running on battery power will be activated. Reset this alarm by depressing the RESET key in the alarms section of the keypad.
5. Make note of the time and the battery voltage.
6. Allow the A*CAT*®1 to operate in this condition for 60 minutes. After 60 minutes the battery voltage should be 11.8 volts DC or higher (12.1 volts DC or higher if optional second battery is installed). If the battery voltage is 11.8 (12.1) volts DC or higher proceed to step 7. If the battery voltage is below 11.8 (12.1) volts DC after 60 minutes of pumping, the batteries are not providing full capacity and must be replaced.
7. Press PUMP OFF and power down the A*CAT*®1. Restore AC power by connecting the AC plug of the A*CAT*®1 to a proper AC receptacle. Allow the system to recharge the batteries for at least four hours.

   Note: *It is not necessary to power down the* A*CAT*®1 *System in order to charge the batteries. Proper charging will take place whether the* A*CAT*®1 *is powered up or powered down as long as the system's AC plug is connected to a proper AC outlet.*

Battery Replacement Procedure

1. Switch the IABP off using the front panel power switch.
2. Switch off the DC circuit breaker and remove AC power from the unit by unplugging it from the wall outlet.
3. Remove the right side cover of the unit by pulling down on the two retaining clips under the bottom edge of the panel. Lift the side cover off of the A*CAT*®1.
4. On the right side of the unit, disconnect the two quick-disconnect plugs for the batteries, one for the positive lead and one for the negative lead.
5. Remove the two screws holding the front edge of the battery retaining bracket to the bottom panel of the unit's base.
6. Lift the front edge of the battery retaining bracket and remove the battery bracket.
7. Lift the battery out and remove it. Exercise caution to ensure that the battery's positive and negative leads do not touch any part of the unit while pulling the battery out.
8. Transfer the positive and negative power leads from the battery that was removed to the battery that is about to be installed. Be certain to connect the proper color wire to the proper battery terminal lead. The BLACK lead to the NEGATIVE terminal of the battery and the RED lead to the POSITIVE lead of the battery.
9. Install the battery into the left side of the unit. It should be installed in the same manner as the battery which was removed.
10. Secure the battery retaining bracket by reinstalling the two screws.
11. Connect the two quick-disconnect plugs for the batteries, one for the positive lead and one for the negative lead. All quick connect plugs are labeled with either the "+" or "-" symbol. ALWAYS CONNECT "+" to "+" and "-" to "-".
12. Plug the AC connector into a proper AC wall outlet.
13. Switch on the DC circuit breaker.
14. Power on the A*CAT*®1 and measure the battery voltage at the battery. The battery voltage at this point should be between 10 and 14 volts DC. This voltage will vary dependent upon the state of charge of the newly installed batteries. If the batteries are not fully charged the voltage will be lower than 14 volts DC but the voltage should be slowly rising. If the batteries are fully charged the voltage should be at approximately 14 volts. It is recommended that after installing new batteries that the A*CAT*®1 be plugged into a proper AC outlet for at least four hours to charge the batteries.
15. Reinstall the side cover of the unit.

Service Information

If the A*CAT*®1 requires preventive or corrective maintenance service, or if you need assistance with an operational problem, call your Arrow International Field Service Representative. You can receive clinical/technical assistance 24 hours a day by calling:

1-800-447-6961 (U.S.A. & Canada)
or
1-617-389-8628
(outside the U.S.A. & Canada)

Ordering Parts, Supplies, Options and Accessories

You can order parts, supplies, options and accessories by calling or writing Arrow International:

Arrow International, Inc.
Customer Service Department
2400 Bernville Road
Reading, PA 19605

1-800-523-8446
Orders Only FAX: 1-800-343-2935

1-610-478-3196
Fax: 1-610-478-3195
(Outside the U.S.A. & Canada)

Call or write to verify prices before ordering. The order should specify item name, part number, price and quantity. The catalog number for the A*CAT*®1 is IAP-0100.

ORDERING INFORMATION

Name	Catalog Number	Description
ECG cables	IAA-06031	Complete three lead ECG cable consisting of one IAA-06032 with one IAA-06034 (12 ft.\3.5m)
	IAA-06032	Three lead main trunk cable (8.5 ft.\2.5m)
	IAA-06034	Three lead patient cable, clip ends (39 in.\1m)
	IAA-06035	Extended length three lead main trunk cable (12 ft.\3.5m)
	IAA-06036	Complete extended length three lead ECG cable consisting of one IAA-06035 with one IAA-06034 (15 ft.\4.5m)
	IAA-06037	Complete five lead ECG cable consisting of one IAA-06038 with one IAA-06039 (15 ft.\4.5m)
	IAA-06038	Five lead main trunk cable (11.5 ft.\3.5m)
	IAA-06039	Five lead patient cable, clip ends (39 in.\1m)
ECG Back Pad Cable	IAA-04303 3 lead IAA-04305 5 lead	For use with NDM backpad electrode
Backpad Electrode	01-3130 3 lead (infant) 01-4130 3 lead (adult)	For use with NDM backpad cable NDM/Conmed Customer Service numbers: 800-448-6506, 513-294-1767 or 315-797-8375
Phono-to-Nicolay cable	IAA-03703	Cable for connecting ECG from monitor to IABP
Phono-to-Phono cable	IAA-00003	Cable for connecting ECG or AP monitor to ECG MON or ART PRESS connector on the A*CAT*®1 (25ft.)
Phono-to-4.4mm Bantam	IAA-03712	For connection of AP signals from Spacelabs monitors or other monitors using 4.4mm connectors (25 ft.\7.7m)
Nicolay-to-4.4mm Bantam	IAA-03713	Cable for connecting ECG signal from Spacelabs monitors or other monitors using 4.4mm connectors (25 ft.\7.7m)
Recorder Paper	IAA-09004	10-roll box of 50mm blank paper thermal-sensitive paper for the A*CAT*®1 strip chart recorder (275ft./roll)
Helium tanks	IAH-09045	Case of 4 disposable canisters, 33 liters at 500psi
	IAH-09047	HZL type refillable tank with standard yoke fitting and European approval*, 100 liters at 2900psi
	IAH-09048	HZL type refillable tank with standard yoke fitting and US approval, 106 liters at 2200psi
Helium Tank Adapter with Retaining Hardware	IAH-09145	Adapter which allows the 500 psi disposable helium tank to be used in the standard yoke

* BAM approved Post Medical Valve. Meets ECC requirements for Belgium, France, Germany, Netherlands, and U.K.

ORDERING INFORMATION (continued)

Name	Catalog Number	Description
Umbilical Cord	96-3701-001	Monitor to Control Unit Cable, 12 ft.
Model 2701 IAB Simulator	IAT-00010 (115V) or IAT-00011 (220V)	Interactive hemodynamic ECG/AP/Auxiliary Pressure training simulator; battery operated, computer-based training system produces synchronized ECG, AP and auxiliary pressure waveforms at different pulse rates, including dysrhythmias, when used with A*CAT*®1; includes battery charger, three phono-RCA cables and one phono-Nicolay cable (6 ft.)
AC charger	IAT-00020	115 Volt AC Charger for the Arrow International Model 2701 IAB Simulator
AC charger	IAT-00021	220 Volt AC Charger for the Arrow International Model 2701 IAB Simulator
Load Simulator	IAT-00025	Load simulator to simulate IAB attached to the A*CAT*®1 IABP System
Hydraulic Load Simulator	IAT-00012	Hydraulic load simulator to simulate IAB attached to the A*CAT*®1 IABP system
Operator's Manual	IAM-9001*	A*CAT*®1 Operator's Manual
Service Manual	IAM-9002	A*CAT*®1 Service Manual
IV Pole Mounting Bracket	IAA-00170	Allows mounting of the A*CAT*®1 Control Module on any standard IV pole
Aircraft Lockdown Bracket	IAA-00100	Allows the mounting of the A*CAT*®1 into the Brownline Track System of an aircraft
Helium Washer	2500-9085-002	Seals the gas connection between the yoke and the helium tank or the helium tank adapter
Power Cords	IAA-09650	Detachable power cord with North American plug configuration (12 ft.\3.5m)
	IAA-09660	Extended length detachable power cord with North American plug configuration (15 ft.\4.5m)
	IAA-09670	Detachable power cord with continental European plug configuration (8.2 ft.\2.5m)
	IAA-09680	Extended length detachable power cord with continental European plug configuration (15 ft.\4.5m)
AC Fuse	4300-0002-003	5 x 20mm AC fuse rated at 5 ampere 250 volt
Battery	4000-9022-001	12 Volt battery for DC operation

* Specify manual language: English (-), French (F), German (D), Italian (I), Japanese (J), or Spanish (E).

The A*CAT*®1 One-Year Limited Warranty

Arrow International, Inc. (ARROW) warrants the ARROW A*CAT*®1 Intra-Aortic Balloon Pump against defects in materials and workmanship for a period of ONE (1) YEAR from the date of purchase. If ARROW receives notice of such defects during the warranty period, ARROW will, at its option for the original customer, repair or replace products which prove to be defective.

Exclusions

The above warranty shall not apply to defects resulting from: (a) repairs by an unauthorized party; (b) improper maintenance by the customer; (c) modifications made without written permission of ARROW; (d) damage by accident, abuse, misuse, or misapplication; (e) operation otherwise than in accordance with instructions furnished by ARROW; or (f) if the serial number has been altered, defaced or removed.

Obtaining Warranty Service

To obtain warranty service, please call Arrow International's Intra-Aortic Balloon Product Hotline 24 hours a day at 1-800-447-6961 or 1-617-389-8628 (outside the U.S.A. or Canada).

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The A*CAT*®1 has internal diagnostic mechanisms to notify you of console or catheter malfunctions. The possible causes and suggested corrective actions will be displayed on the LCD. It is important to pay attention to alarms and to respond immediately if the pump shuts down. If the pump shuts down, the balloon will deflate automatically. However, allowing a deflated balloon to remain dormant is hazardous. A deflated balloon does not provide valuable cardiac support to the patient and thrombus formation can occur if blood becomes trapped in the folds of the deflated balloon.

If a pump shutdown occurs, note the time and call hospital personnel knowledgeable in the maintenance of the A*CAT*®1. If repair and pumping cannot be accomplished within 15-30 minutes, use a 50/60 cc syringe to rapidly inflate and deflate the balloon several times. This will reduce the risk of thrombus formation, but should be used only as an emergency procedure for short periods of time while awaiting the physician's arrival. The physician should consider removing the balloon. Arrow International recommends that you have a back-up IABP system available in case of a pump shutdown.

The troubleshooting tables in this chapter are designed to help you identify and correct problems quickly. In addition, you can identify and correct helium leaks by following the Leak Testing procedure described. If you are unable to correct EMI or any other problem with your system, call your local Arrow International Field Service Representative or call our 24-hour IABP service hotline 1-800-447-6961 or 1-617-389-8628 (outside the U.S.A. & Canada).

In addition, help is available for most functions. Simply press the HELP key for startup help or press a FUNCTION key followed by HELP for specific key-related information.

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Common Operational Problems

The table below describes the possible causes and corrective actions for many common operational problems. Where appropriate, there are references to sections in this manual for further information. If you do not find your problem in this table look in the other troubleshooting tables in this section. Always respond immediately to a pump shutdown.

COMMON OPERATIONAL PROBLEMS

Problem	Possible Cause(s)	Corrective Actions
Console does not turn on when power switch is pressed	Power cord not connected to AC power and batteries completely discharged	Connect power cord to an active AC power supply and press power switch (Section 8.1)
	Console fuse blown	Contact qualified hospital personnel or your Arrow International Field Service Representative; use correctly rated fuses only
Pump operates in AC power but does not operate in battery	Circuit breaker switched off	Switch on circuit breaker in helium compartment
No audible tone for control keys	Volume control too low	Use AUDIO LEVEL in multi-function keys to raise the volume (Section 3.3). Key tone and alarm tone may be set independently.
No flashing heart symbol on LCD	Invalid trigger selected	Change trigger mode.
	ECG too small	Autogain may be insufficient—increase ECG gain via MAN gain
No ECG waveform displayed	Incorrect ECG source selected	Check ECG signal source, then select that ECG lead - i.e. I, II, III, AVR, AVL, AVF, V (Section 5.1).
	Defective connections	Check electrodes and cable connections; repair or replace as required

COMMON OPERATIONAL PROBLEMS		
Problem	**Possible Cause(s)**	**Corrective Actions**
No ECG waveform displayed (cont.)	Monitor connected improperly	Make sure monitor connected via Phono-to-Phono cable to ECG MON input connector (Section 5.1)
	Defective ECG skin amplifier	Use an external ECG monitor connected to the ECG MON input connector to monitor ECG; call Arrow International for service (Section 8.2)
	Defective waveform display	Use the strip chart recorder or an an external monitor connected to the ECG output connector to monitor ECG; call Arrow International for service (Section 8.2)
	Incorrect ECG Source selected	Check ECG signal source LED. Change source by pressing SELECT key.
AC interference in ECG waveform (50/60Hz interference)	Reference electrode detached	Reattach reference ECG electrode
	Poor electrode contact, attach new electrodes to patient	
	Lead wires close to AC source	Bundle ECG lead wires together and route them close to patient
	Inappropriate trigger mode selected	Select another trigger mode (Section 5.1)
Noisy ECG	Excessive muscular artifact	Check electrode contacts and disposable electrode sites; place electrodes on bony prominences (Section 5.1)
	Skin inadequately prepared	Repeat skin preparation, then apply new electrodes (Section 5.1)
	Electrodes placed improperly	Apply new electrodes to proper locations (Section 5.1)
Wandering ECG baseline	Poor electrode contact	Attach new electrodes
	Respiratory movements picked up by patient cable yoke	Move the patient cable yoke away from the abdomen and ventilator equipment

COMMON OPERATIONAL PROBLEMS

Problem	Possible Cause(s)	Corrective Actions
Wandering ECG baseline (cont.)	Electrodes placed improperly	Apply new electrodes to proper locations (Section 5.1)
No AP waveform displayed	Catheter or needle occluded	Flush and fill the catheter
	Defective transducer	Replace pressure transducer
	Defective amplifier	Use external AP monitor connected to the ART PRESS input connector to monitor Arterial Pressure; call Arrow International for service (Section 8.2)
	Incorrect source selected	Check AP signal source LED. Change source by pressing SELECT key.
	Defective waveform displayed	Use strip chart recorder or an external monitor connected to the the ART PRESS output connector to monitor Arterial Pressure; call Arrow international for service (Section 8-2)
Transducer cannot be zeroed or calibrated	Defective transducer	Replace transducer
	Improper calibration procedure attempted	Disconnect all AP pressure cables and press the RESET key. Reconnect AP cables and follow calibration instructions in Section 6.1
Zero baseline drifts	Defective transducer	Replace transducer
Erratic pressure display	Defective transducer	Replace transducer
Helium loss	Leak in pneumatic system or in balloon	Perform Leak Test and repair as necessary (Section 9.1)
	Blood in catheter	Stop pumping and remove balloon immediately

Diagnostic Alarms

The A*CAT*®1 alarm system notifies you of certain potential or actual problems and suggests corrective steps: always respond to alarms promptly. The tables on the following pages provides additional information about the automatic response and information only alarms.

1. To disable alarms, press the OFF control key in the ALARMS section of the keypad twice. This will disable all Class 1 alarms except SYSTEM ERROR for ten minutes. Subsequent depressions of this control key add ten minutes to the disable period, up to 60 minutes.

WARNING

Do not turn off alarms except for brief period while correcting an alarm condition. After the alarm condition has been corrected, enable the alarms by pressing the ALARMS ON control key.

2. To change the audio level, select AUDIO LEVEL in the multi-function keys of the keypad and adjust appropriately.

AUTOMATIC RESPONSE ALARMS (Class I)

Alarm	Possible Cause(s)	Corrective Actions
SYSTEM ERROR	Fault in computer system	Press the ALARM RESET control key; press the PUMP STBY control key, then PUMP ON (correcting this alarm may require turning the power off and on to reset the microprocessor. All Control Key Settings are retained in memory for five minutes and need not be reset). If the alarm recurs, call Arrow International for service (Section 8.2)

AUTOMATIC RESPONSE ALARMS (Class I)

Alarm	Possible Cause(s)	Corrective Actions
POSSIBLE HELIUM LEAK	Leak in tubing or connections	Perform Leak Test and repair as needed (Section 9.1)
	Kinked catheter	Find kink and straighten out the catheter. Be sure that the IAB membrane has fully exited the insertion sheath.
	Balloon connector not properly seated	Reconnect balloon connector to console (Section 5.1)
	Blood in catheter tubing	Remove balloon immediately and insert a new IAB catheter **WARNING** **Any evidence of blood leakage within the IAB assembly warrants immediate IAB removal.**
	Very late deflation or early inflation	Change to 1:2 assist. If alarm condition does not occur, return to 1:1 and adjust timing so BPW deflation baseline may be observed. Note: If possible He loss continues in 1:2, perform leak test described later in this section.
LARGE HELIUM LEAK DETECTED	IAB catheter Quick Connect Valve not tightly connected	Tighten connection at Quick Connect Valve
	Leak at catheter connection or in Tygon tubing between console and catheter insertion point	Check all connection points leaks and correct as required (Section 9.1)
	Other helium leak	Perform Leak Test and repair as necessary (Section 9.1)

AUTOMATIC RESPONSE ALARMS (Class I)		
Alarm	**Possible Cause(s)**	**Corrective Actions**
PURGE FAILURE	Helium tank not inserted properly	Reinsert tank per instruction (Section 8.1)
	Helium tank empty	Replace with full helium tank (Section 8.1)
	Reliable trigger signal lost	• Check electrode contacts • Check for broken electrical connections on electrodes and leads • Check to make sure correct trigger source selected • Select another trigger mode to obtain reliable triggering • Check the patient
	Balloon not connected to console	Connect balloon to BALLOON CONNECTOR on front of console (Section 5.1)
HIGH BASELINE	Kinked catheter	Find kink and straighten out the catheter. Be sure that the IAB membrane has fully exited the insertion sheath
	Partially wrapped balloon	Notify physician; inject 50 cc of air into the balloon connector and aspirate it immediately
	Overfill	Call Arrow International for service (Section 8.2)

AUTOMATIC RESPONSE ALARMS (Class I)		
Alarm	**Possible Cause(s)**	**Corrective Actions**
HIGH PRESSURE	Kinked catheter	Find kink and straighten out the catheter. Be sure that the IAB membrane has fully exited the insertion sheath
	Partially wrapped balloon	Notify physician; connect a 50/60 cc syringe to balloon connector and manually inflate and deflate IAB several times
	Balloon too large	Decrease IAB volume until waveform returns to normal configuration (Section 9.1). **NOTE:** **The ACAT®1 software trends the unwrapping sequence to determine if and when the IAB is unwrapped. This process occurs *only* at the *initial start-up* following POWER ON.** **WARNING** **If an IAB is suspected of being occlusive, do not reduce the IAB volume to less than 2/3 of the balloon's capacity. To prevent thrombus formation, pump the balloon at its maximum capacity for five minutes every hour. A smaller IAB volume should be considered.**
AUTOMATIC RESPONSE ALARMS (Class II)		
PRESSURE TRIGGERING LOSS	No pressure waveform displayed	• Check patient's state • Check all connections • Check pressure transducer, catheter and connections for loose connections; repair if necessary • Make sure that correct pressure source is selected • Select another trigger mode • Check AP waveform source and change if needed

AUTOMATIC RESPONSE ALARMS (Class II)		
Alarm	**Possible Cause(s)**	**Corrective Actions**
ECG TRIGGER LOSS	No ECG waveform displayed	• Check patient rhythm • Check electrode placement and change if necessary • Check cable connections; reconnect if necessary • Check external monitor connections at monitor and at ECG MON input connector • Check lead selection • Check patient • Check ECG source selection, change if needed
	Waveform erratic or noisy	Reapply electrode paste or replace disposable electrodes
	Low waveform amplitude or biphasic QRS complexes	• Select another lead (if using an external monitor, use monitor's controls to select a different lead) • Increase size using MAN gain
	Inappropriate trigger mode selected	Select another trigger (readjust timing if you select ART PRESS trigger mode)
ECG LEAD FAULT DETECTED	Poor electrode contact	Reapply electrode paste or replace disposable electrodes
	Loose cable connections	• Check cable connections; repair if necessary • Replace ECG cable
STANDBY >3 MINUTES	Pump has been left in STANDBY for more than 3 minutes	• Press ALARM RESET to clear the alarm (alarm will reoccur in 3 minutes) • Press PUMP OFF • Press PUMP ON to resume counterpulsation • Press PUMP STBY twice to place pump in STANDBY mode indefinitely

INFORMATION ONLY ALARMS (Class III)		
Alarm	**Possible Cause(s)**	**Corrective Actions**
DEFLATION >100%	Deflation set beyond 100% of R-R interval	Check timing in relation to AP waveform; adjust if necessary (Section 5.1)
DRAIN FAILURE	Condensate collection bottle full or the tubing is kinked	Empty condensate collection bottle (Section 8.1). Straighten tubing.
	Drain valve failed to open or system purge not performed	• Initiate purge cycle by pressing PUMP OFF, then PUMP STBY; wait 5 sec for purge, then press PUMP ON to restart pumping • Call Arrow International for service (Section 8.2)
BATTERY LIFE LESS THAN 20, 10, 5 MINUTES	Batteries will be completely discharged in 20, 10 or 5 minutes	Connect system to AC power as soon as possible to recharge batteries
SYSTEM RUNNING ON BATTERY	System accidentally or intentionally disconnected from AC power	Reconnect system to AC power as soon as possible.
	AC power failure	Arrange for alternate AC power source if failure expected to exceed 90 minutes.
BATTERY INOPERATIVE	The A*CAT*®1 will not run in battery mode due to a faulty battery circuit breaker	Do not disconnect the A*CAT*®1 from the AC power source. Check the DC circuit breaker located in the helium compartment. (Section 8.1)
TIMING ERROR	Insufficient time to deflate balloon before next inflation cycle	Check timing in relation to AP waveform; adjust as necessary (Section 5.1).
ECG WAVEFORM DETECTED IN INTERNAL TRIGGER	Patient has ECG complex	Verify ECG, change trigger mode.

INFORMATION ONLY ALARMS (Class III)		
Alarm	**Possible Cause(s)**	**Corrective Actions**
LOW HELIUM SUPPLY	Helium tank pressure less than 100psi	Install a full helium tank (Section 8.1)
	Helium tank inserted improperly	Remove and replace helium tank per instructions (Section 8.1)
LOW BATTERY FOR STATIC RAM	The internal RAM battery needs replacement	Place service call (Section 8.2)

ESIS

ESIS minimizes the interference problems caused by electrosurgical/cautery devices. However, some ESU devices cause more severe interference problems than others: in some cases, particularly with older cautery systems, completely eliminating interference with the ECG waveform may not be possible. The table below provides suggestions for correcting excessive interference problems.

TROUBLESHOOTING ESIS

Problem	Possible Cause(s)	Corrective Actions
Persistent electrosurgical interference	Poor ECG lead contact	• Check electrode-to-skin contact; reattach electrode if necessary • Check connections at lead tip and cable junctions; repair if necessary • Replace the ECG cable • Use back pad electrode
	Incorrect ECG lead selected	Change lead selection in the ECG SOURCE SELECT section of the keypad
	Lead wires positioned improperly	Place lead wires so they are away from the electrocautery cable and at a 90° angle from the cables
CAUTION: ESIS is operational at all times, however, it is most effective when a three- or five-lead ECG cable is used	High electrocautery setting	• Use minimum ESU required for adequate cutting and setting • Change to ART PRESS trigger mode
	Ground plate positioned improperly	Place ground plate under back and under the surgical site
	Electrodes placed on patient improperly	Change electrode placement (leads may be placed on the posterior aspect across the shoulder axis if necessary); check lead selection
Persistent electrosurgical interference	Cables placed improperly	Place cables so they are away from the electrocautery cable and at a 90° angle from the cables
Display scrambled or corrupted	Excessive ESU Interference	Disconnect cable from LCD unit momentarily and reattach

TROUBLESHOOTING ESIS		
Problem	**Possible Cause(s)**	**Corrective Actions**
Absent or poor ECG waveform	ECG Cable connected improperly	Make sure the ECG cable is connected to the correct connector on the A*CAT*®1 (Section 5.1)
	Poor ECG lead contact	• Check electrode-to-skin contact; reattach electrodes if necessary
	Incorrect lead selected	• Check connections at lead tip and cable junctions; repair if necessary
	ECG source improperly selected	• Check ECG source and change if needed
	Electrodes placed on patient improperly	Check electrode placement (leads may be placed on the posterior aspect across the shoulder axis if necessary); check lead selection
Intermittent or absent flashing heart or white trigger bands	Inappropriate trigger mode selected	Change trigger mode

Balloon Pressure Waveform

The balloon pressure waveform displayed on the A*CAT*®1 LCD represents the dynamic actions of the helium shuttle gas during pumping. A properly functioning balloon usually produces the balloon pressure waveform and AP waveform shown in Figure 9.1.

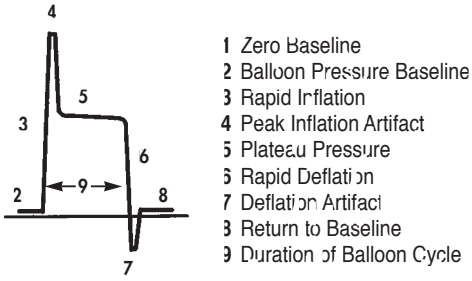

Figure 9.1A: Normal Balloon Pressure Waveform

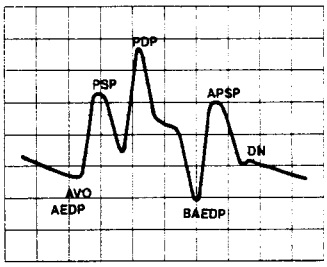

Figure 9.1B: Properly Timed Arterial Pressure Waveform

Problems with the control system, IAB problems or certain patient conditions can cause distortions in the balloon pressure waveform. Troubleshooting these waveforms is often the best way to recognize and correct problems. Being familiar with the waveforms in this section can help you maximize the clinical benefits of IABP to the patient.

Some of the abnormal balloon pressure waveforms in this section may initiate one or more alarms. This is because the A*CAT*®1 detects incorrect pumping volume, abnormally high balloon pressure, helium loss and catheter or tubing obstructions by monitoring balloon pressure. By monitoring the patient's status as well, the A*CAT*®1 can identify balloon occlusion and reduced augmentation.

The BPW plateau has a normal and expected relationship to the PDP of the patient. The BPW plateau and PDP should be within 20-25 mmHg of each other. You may want to use the cursor to verify the BPW plateau pressure.

Squared Waveform

Three causes of a squared balloon pressure waveform (Figure 9.2) are listed below.

1. There is a kink in the catheter, sheath or balloon membrane.

   Examine the catheter for kinks, then straighten out the catheter. Verify that the IAB membrane has completely exited the insertion sheath.

2. The balloon has not unwrapped.

   Notify the physician. Inject approximately 50 cc of air into the balloon connector and aspirate it immediately.

3. The IAB is occlusive.

   Press the OFF control key in the PUMP STATUS section of the keypad. Select BALLOON VOLUME and decrease the balloon inflation volume. Observe the balloon pressure waveform. Repeat this procedure until the waveform appears normal.

WARNING

If an IAB is suspected of being occlusive, do not reduce the IAB volume to less than 2/3 of the balloon's capacity. To prevent thrombus formation, pump the balloon at its maximum capacity for five minutes every hour. A smaller IAB volume should be considered.

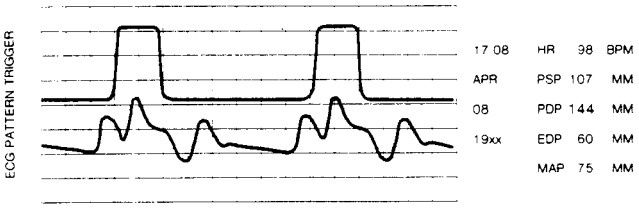

Figure 9.2: Squared Balloon Pressure Waveform

Reduced Augmentation

Reduced augmentation may result in a waveform characterized by a "low plateau pressure" (see Figure 9.3). Some causes of reduced augmentation are listed below.

1. **Balloon too small -**
   Forward displacement of blood will be decreased since the blood will also be driven around the balloon.
2. **Balloon positioned too low -**
   If the balloon is too low there is more area to try to displace volume and the balloon is not as effective.
3. **Hypovolemia - Patient is ready to wean from the IABP -**
   Rationale: Best augmentation occurs when the patients stroke volume equals the balloon volume, ie. 40cc balloon will work best when patients stroke volume is 40cc's. If the stroke volume goes above or below the balloon volume the augmentation will decrease.
4. **Balloon is not unwrapped -**
   If the balloon is not fully unwrapped it will be unable to displace the full volume and therefore augmentation will decrease.
5. **Late inflation -**
   When inflation occurs at the beginning of diastole there is a lot of blood in the aorta because systole has just occurred. If the balloon inflates too late, the blood in the aorta will run off into the periphery and therefore will not have as much volume to displace.
6. **Balloon positioned in the wall of the aorta instead of the vessel -**
   This would cause a false aneurysm, and the patient would most likely experience severe back pain. This would cause a decrease in augmentation because there would be minimal, if any, displacement of blood.
7. **Balloon volume not set at desired value -**
   All pumps automatically set volume when balloon is connected, however the balloon volume may have been decreased and not returned to full volume.
8. **Low systemic vascular resistance (SVR).**

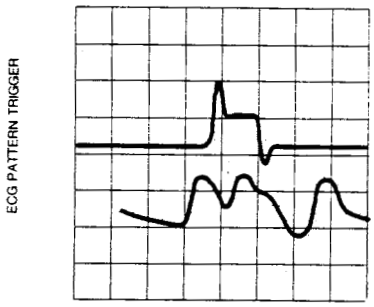

Figure 9.3: Balloon Pressure Waveform Reflecting Reduced Augmentation

Baseline Below Zero

If the baseline of the balloon pressure waveform falls below zero as shown in Figure 9.4, there is probably a helium loss. The A*CAT*®1 will initiate the POSSIBLE HELIUM LOSS or LARGE HELIUM LEAK alarm (unless the system is in the ALARMS OFF mode). To correct this problem:

1. Press PUMP OFF to stop the pump.
2. Perform the Leak Test (Section 9.1) and repair any leaks found. Do not resume pumping until leaks have been corrected.

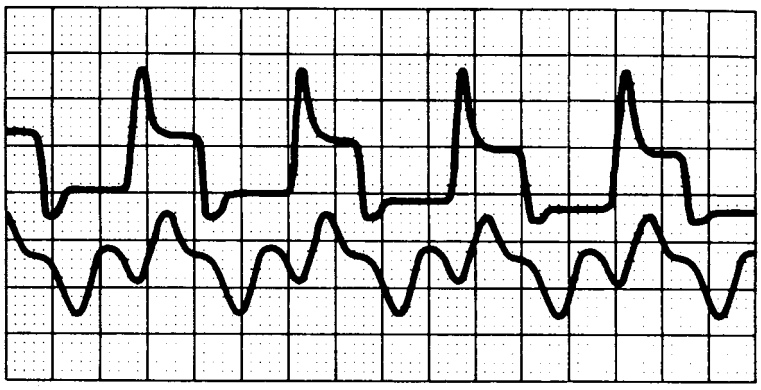

Figure 9.4: Balloon Pressure Baseline Below Zero

Leak Testing and Tubing Repairs

If a helium leak is suspected, follow the instructions below to check the pneumatics and the balloon connector. You will need a pair of rubber-shod hemostats and a spare balloon connector and tubing to perform the Leak Test. Call your Arrow International Sales Representative or service number for ordering information.

Leak Test

1. Press the RESET control key in the ALARMS field to silence any audible alarms.
2. Press the ALARMS OFF control key twice to disable the alarms for ten minutes.

   Pressing this control key several times will increase the ALARMS OFF period by 10-minute increments, up to 60 minutes.
3. Use a pair of rubber-shod hemostats or other clamping device to clamp the catheter tubing between the quick connect valve and the bifurcation.
4. Press the ON control key to start pumping.
5. Observe the balloon pressure waveform. If the baseline falls, the leak is probably between the pump and the clamp. If the baseline does not fall, the leak is probably on the patient side: consider stopping the pump, removing the balloon catheter and inserting another catheter.
6. Press the PUMP OFF control key and remove the hemostat.
7. Check the 0-rings on the balloon connector, wipe off any debris and make sure that the connection at the quick connect valve is tight.

   Also, examine the tubing at the balloon connector and at the catheter junction. If the tubing appears to be stretched in either location, see the instructions below to repair the tubing.
8. Repeat steps 2-4. If the baseline remains steady, the leak has been corrected and you can resume pumping. If the baseline continues to fall, the leak is in the control system or the connector. Complete steps 9-10.
9. Press the PUMP OFF control key and remove the hemostat.
10. Remove the balloon connector, cut off 1/2" of tubing, replace the connector and repeat steps 2-4. If the baseline remains steady, the leak has been corrected and you can resume pumping. If the baseline continues to fall, there may be an internal console leak. Call Arrow International for service.
11. If the alarms are still disabled, press the ON control key to re-enable the alarms.
12. Press ALARM RESET to remove alarm messages.

Tubing Repairs

1. To repair a tubing leak, wrap non-porous tape (e.g., electrical tape) around the tubing at the site of the leak.
2. To repair stretched tubing at the balloon connector, remove the compression ring and pull the connector off the tubing. Then cut off a 1/2 inch segment from the end of the tubing and reconnect the balloon connector and the compression ring.
3. To repair stretched tubing at the catheter junction, disconnect the tubing from the junction. Then cut a 1/2 inch segment from the end of the tubing and reassemble the junction.

If the leak is found at the QUICK CONNECT, Op-Site® or other occlusive, clear dressing material may be used to repair the leak.

Many terms associated with the use of Intra-Aortic Balloon Pumping are referred to by their abbreviations. This list is provided for your reference.

AEDP	Aortic End-Diastolic Pressure
AFIB	Atrial Fibrillation
AMI	Acute Myocardial Infarction
AP	Arterial Pressure
APSP	Assisted Peak Systolic Pressure
A/V	Atrio-Ventricular (as in pacemaker)
AVC	Aortic Valve Closure
AVO	Aortic Valve Opening
BAEDP	Balloon Aortic End-Diastolic Pressure
BPM	Beats Per Minute
CAD	Coronary Artery Disease
CO	Cardiac Output
CPP	Coronary Perfusion Pressure
CVP	Central Venous Pressure
DN	Dicrotic Notch
ECG (also EKG)	Electrocardiogram
EDP	End-Diastolic Pressure
ESIS	Electrosurgical Interference Suppression
ESU	Electrosurgical Unit(s)
HR	Heart Rate
IAB	Intra-Aortic Balloon
IABP	Intra-Aortic Balloon Pump (or Intra-Aortic Balloon Pumping)

IEC	International Electrical Code
IVC	Isovolumetric Contraction
IVR	Isovolumetric Relaxation
LAP	Left Atrial Pressure
LCA	Left Coronary Artery
LVEDP	Left Ventricular End-Diastolic Pressure
MAP	Mean Arterial Pressure
MI	Myocardial Infarction
MVO2	Myocardial Oxygen Consumption
PAD	Pulmonary Artery Diastolic Pressure
PAEDP	Patient Aortic End-Diastolic Pressure
PAP	Pulmonary Artery Pressure
PCWP	Pulmonary Capillary Wedge Pressure
PDP	Peak Diastolic Pressure
PSP	Peak Systolic Pressure
SaO2	Blood Oxygen Saturation Level
SV	Stroke Volume
SVR	Systemic Vascular Resistance
UL	Underwriter's Laboratories
VSD	Ventricular Septal Defect

Afterload	The pressure which ventricular contraction must exceed to open the aortic valve; Aortic End-Diastolic Pressure
Aortic End-Diastolic Pressure (AEDP)	The pressure in the aorta immediately prior to the opening of the aortic valve
Aortic Valve Closure (AVC)	The onset of diastole; signaled by the DN on the AP waveform
Aortic Valve Opening (AVO)	The onset of systole; signaled by the beginning of the upstroke on the AP waveform
Assisted Peak Systolic (APSP)	Systolic pressure that shows the effect on the pressure by balloon action; usually lower than the unassisted PSP
Augmentation	The increase in diastolic blood pressure that occurs when balloon inflation displaces ejected blood both back toward the heart and distally toward the peripheral vasculature
Balloon	See Intra-Aortic Balloon
Balloon Aortic End-Diastolic Pressure (BAEDP)	The lowest pressure in the aorta caused by balloon deflation
Balloon Pressure Waveform	The waveform that depicts the pressure of helium in the balloon during each inflation and deflation cycle; displayed as the blue (3rd) waveform on the LCD
Cardiac Output (CO)	The volume of blood ejected from the right or left ventricle per minute; equal to the Stroke Volume multiplied by the Heart Rate
Cold Trap	The internal mechanism that removes water vapor from the IAB catheter and pneumatic tubing; this water normally accumulates during IABP operation
Counterpulsation	The balloon-generated pulse that occurs in a cycle counter to the normal cardiac pulse; counterpulsation is controlled to increase diastolic pressure and decrease End-Diastolic Pressure
LCD	The waveform display that displays the ECG, AP and balloon pressure, as well as physiological data, operating instructions and alarm messages
Diastole	The phase of the cardiac cycle in which most coronary perfusion and ventricular filling occur
Dicrotic Notch (DN)	The notch on the downslope of the AP waveform that signals AVC and the onset of diastole; caused by the backflow of blood as the pressure in the ventricle falls below that in the aorta

Ejection	The bolus of blood forced out of the heart and into the aorta by ventricular contraction
Electromechanical Delay	The difference in time between electrical events of the heart (e.g., ventricular depolarization) and the resulting mechanical event (e.g., ventricular contraction)
Electro-Surgical Interference Suppression (ESIS)	A filtering function to minimize interference on the ECG waveform caused by electrosurgical or electrocautery devices
Filling	The collection of blood in the ventricles prior to isovolumetric contraction
Flash Card	PCMCIA standard for storing data or downloading custom setups
Heart Rate (HR)	The number of cardiac cycles per minute
Intra-Aortic Balloon (IAB)	The balloon-tipped catheter used for counterpulsation; also called balloon
Isovolumetric Contraction (IVC)	The phase of the cardiac cycle in which ventricular volume remains unchanged while the left ventricle contracts; enough pressure is generated to overcome aortic pressure (afterload) and cause Aortic Valve Opening
Isovolumetric Relaxation (IVR)	The phase of the cardiac cycle in which most coronary perfusion and ventricular filling occur
Mean Arterial Pressure (MAP)	A measure of Arterial Blood Pressure determined by calculating the area under the curve of the Arterial Pressure Waveform
Nicolay	The manufacturer and type of connection made to the A*CAT*®1 when using ECG skin cables or pressure transducers
Quality Assurance log	Time stamped record of IABP operations including alarms, hemodynamics and operational settings
Patient Aortic End-Diastolic Pressure (PAEDP)	The lowest pressure normally occurring in the aorta; diastolic pressure
Peak Diastolic Pressure (PDP)	The highest aortic pressure generated by balloon inflation; augmented diastole or augmentation; usually higher than PSP
Peak Systolic Pressure (PSP)	The highest aortic pressure produced by ventricular ejection; systolic pressure

Phono-to-Phono	The cable used to connect signals from a patient monitor to the A*CAT*®1
Preload	Ventricular End-Diastolic Volume; measured as LVEDP=PCWP=PAD
Pulse Rate	The number of pressure pulses per minute; during counterpulsation, equals PSP plus PDP, and the effective pulse rate is twice the Heart Rate (when in 1:1 assist ratio)
Pulse Pressure	The mechanical pulse felt by systemic circulation; during counterpulsation, PDP is often higher (or noted before) BAEDP, affecting pressure readings by cuffs and monitoring equipment
Rapid Ejection Phase	The phase of ventricular ejection from just after AVO through PSP (the upstroke on the AP waveform); produces approximately 75% of SV
Stroke Volume (SV)	The volume of blood ejected by the heart during a single systole
Systolic Runoff	The phase of ventricular ejection characterized by a downslope of the AP waveform, between PSP and the Dicrotic Notch; produces approximately 25% of SV
Systolic Unloading	The reduction of afterload seen as a reduction in PSP; however, depression of systolic ejection is also seen as a reduction in PSP
Timing	The synchronization of the balloon-generated pulse with patient hemodynamics; controlled by the IABP operator
Trigger	The signal used by the IABP to activate the inflation/deflation cycle; signal may be patient-generated (ECG or AP) or control system-generated (INTERNAL)

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